

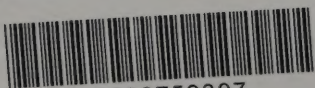
Human Fertilisation and Embryology Authority

Annual Report and Accounts

HC 611
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2007/08

HUMAN
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&
EMBRYOLOGY
AUTHORITY



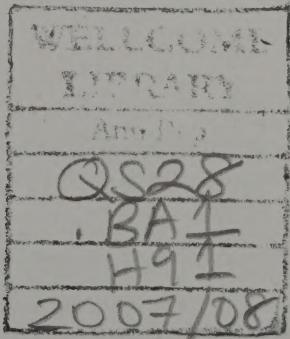
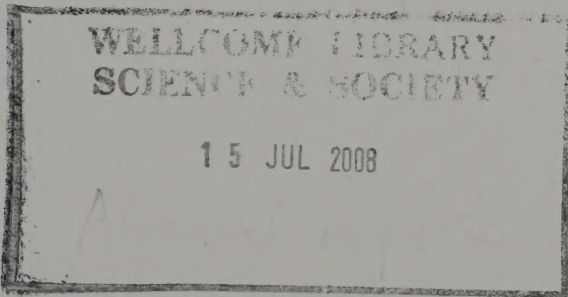
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Presented pursuant Section 6(1) of the Human Fertilisation and Embryology Act 1990

Human Fertilisation and Embryology Authority

Annual Report and Accounts – 2007/08

Ordered by the House of Commons to be printed – 23 June 2008



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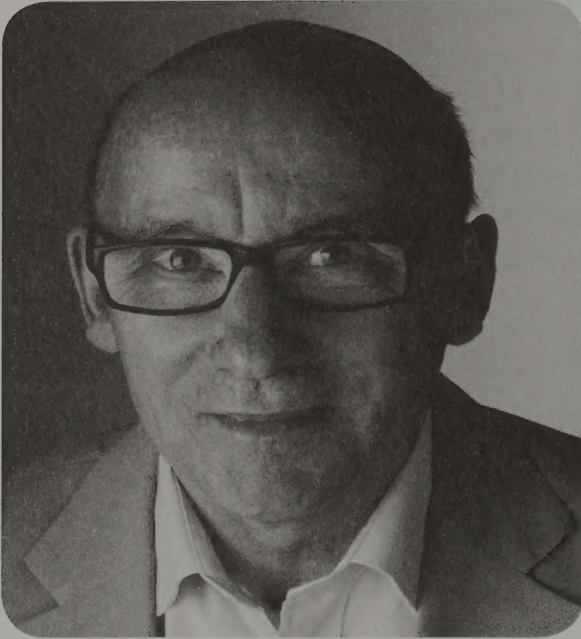
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Alan Doran CB - Interim Chief Executive



Lisa Jardine CBE - Chair

‘We strive to ensure
rigorous safety standards
for patients, embryos and
children born as a result
of Assisted Reproductive
Technologies’

Chair's & Interim Chief Executive's Foreword

The Human Fertilisation and Embryology Authority operates within a fast-moving, complex and ethically challenging area of science. The HFEA's activities attract a consistently high level of public and media interest, particularly in light of the Human Fertilisation and Embryology (HFE) Bill's current passage through Parliament. We strive to ensure rigorous safety standards for patients, embryos and children born as a result of Assisted Reproductive Technologies (ART). Maintaining public confidence in infertility treatment and embryo research remains paramount.

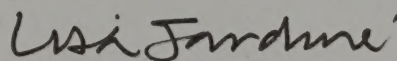
The past year has been a period of high activity and significant achievement. In addition to our normal range of inspection and licensing work, during 2007/08, the HFEA successfully implemented the requirements of the European Union Tissue and Cells Directive for existing clinics and services new to regulation. The 7th edition of the Code of Practice was issued, offering online access for the first time. We have also worked to continue to improve access to a range of reliable and meaningful information and advice available to patients, donors, offspring and the public on the performance of services regulated. This work will continue into 2008/09 in response to legislative changes.

The HFEA remains alert to changes in the external environment. Our policies take into account the wide-ranging and sometimes conflicting views of the public, as well as those of stakeholders from the fertility sector, and beyond. In 2007, the HFEA made important policy decisions on the use of hybrids in research and on multiple births following wide ranging consultations with clinicians, patients and the public. The HFEA also advised the Department of Health on the draft HFE Bill as it took shape and began its passage through Parliament.

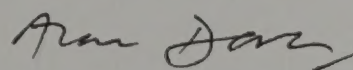
The HFEA remains fully committed to the drive to increase cost effectiveness and to reduce the burden of regulation for clinics. We have worked with the Human Tissue Authority (HTA) to promote ongoing joint working across a range of support functions, in the interests of more streamlined regulation and support services. We are also working to ensure that all our regulatory processes are risk-based and proportionate.

Throughout the year, the HFEA has maintained a robust corporate governance structure, and we have sustained a high level of activity and performance standards during a period of change at the senior level of the organisation. A programme of organisational development (Programme 2010) was initiated in preparation for the implementation of the new HFE Act, which is expected to receive Royal Assent during 2008.

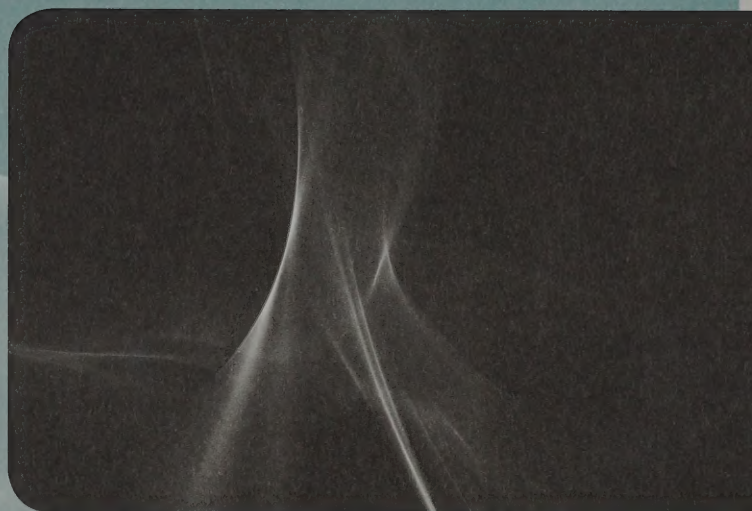
Finally, we would once again like to give our thanks to Authority Members and HFEA staff whose continued hard work and commitment remain key to our success.



Professor Lisa Jardine CBE
Chair

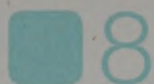


Mr Alan Doran CB
Interim Chief Executive



02 Management Commentary





Management Commentary

About the Human Fertilisation and Embryology Authority (HFEA)

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator overseeing the use of gametes and embryos in infertility treatment and research. The HFEA licenses clinics and research establishments carrying out In Vitro Fertilisation (IVF), donor insemination, other assisted conception procedures and human embryo research, and provides a range of detailed information for patients, professionals, the public and Government.

The HFEA's aim is to be a leading healthcare regulator exercising its functions fairly and proportionately, supplying good quality, relevant and accessible information to all its stakeholders.

The Authority has recently developed the following statement of its purpose and principles:

Purpose

We are the UK's independent regulator of treatment using eggs and sperm, and of treatment and research involving human embryos. We set standards for, and issue licences to centres. We provide authoritative information for the public, in particular for people seeking treatment, donor-conceived people and donors. We determine the policy framework for fertility issues, which are sometimes ethically and clinically complex.

Principles

- We treat people and their information with sensitivity, respect and confidentiality
- We observe the highest standards of integrity and professionalism

- We consult widely - listening to and learning from those with an interest in what we do
- We keep abreast of scientific and clinical advances
- We exercise our functions consistently, proportionately, openly and fairly

Statutory Remit

Within this context, the HFEA has a number of statutory functions. They are based on two specific roles: firstly the licensing and regulation of clinics and research establishments providing treatment, storage and research; and secondly, the maintenance and publication of information about donor treatment and assisted conception.

The current statutory functions are:

- To license and monitor clinics carrying out IVF and donor insemination
- To license and monitor establishments undertaking human embryo research
- To maintain a register of licences held by clinics, research establishments and storage centres
- To regulate the storage of gametes (eggs and sperm) and embryos
- To implement the requirements of the European Union Tissue and Cells Directive (EUTCD) to relicence IVF clinics and to license Intrauterine Insemination (IUI), Gamete Intrafallopian Transfer (GIFT) and other services new to regulation (in 2007)
- To investigate serious adverse incidents and reactions, and to keep a register of serious adverse incidents and serious adverse reactions
- To produce and maintain a Code of Practice, providing guidelines to clinics and research establishments about the proper conduct of licensed activities
- To maintain a formal register of information about donors, licensed treatments and children born as a result of those treatments

- To publicise the HFEA's role and provide relevant advice and information to donor-conceived people, donors, clinics, research establishments and patients, including servicing the statutory right of access to register information
- To review information about:
 - Human embryos and developments in research involving human embryos
 - The provision of treatment services and activities governed by the Human Fertilisation and Embryology (HFE) Act 1990 (or a revised Act, if and when this comes into force)
- To advise the Secretary of State for Health on developments in the above fields where appropriate

Current Operating Context

Over the past few years, the HFEA has been modernising the way it fulfils its regulatory duties, with improvements such as Electronic Data Interchange (EDI) to improve the accuracy of data submitted by clinics and new risk-based inspection methodology.

In 2007/08, a number of pieces of new and recent legislation will profoundly affect the way the HFEA operates in the future. Parliament is currently considering the Human Fertilisation and Embryology (HFE) Bill. Therefore, the HFEA's functions may be subject to change in light of this forthcoming legislation. The new HFE Bill will not only affect what and how the HFEA regulates, but also the range of information the HFEA collects and releases to other people.

There is also now a Regulators' Compliance Code, with which the HFEA must comply, and a continuing drive to reduce the burden of regulation for clinics. In addition, the Regulatory Enforcement and Sanctions (RES) Bill covers the operation of a large number of Government regulators, including the HFEA. This Bill may result in the HFEA becoming eligible to apply for additional powers during the coming year.

To prepare for all of these changes the HFEA is conducting a comprehensive review of its organisational functions in a programme of work called Programme 2010. The HFEA will be involving clinics and other stakeholders in this work as it progresses, to ensure that the organisation's future ways of working will be as efficient and effective as possible.

In light of new Cabinet Office requirements relating to data security, the HFEA will also be ensuring it is fully compliant with the recently introduced information control framework. The HFEA already operates to stringent data encryption standards, restricts the use of removable media, and has conducted penetration testing to ensure that data is secure from external attack. Further information about the HFEA's data security controls can be found in the Statement on Internal Control on page 59.

Longer Term Goals

The current 5 year corporate strategy (published as the HFEA's Corporate Plan for 2004/09), has been regularly reviewed and updated to take into account new legislation and other events with a key impact on the HFEA's role.

The current corporate goals, as set out below, were revised in 2006 to reflect the intention to create a Regulatory Authority for Tissue and Embryos (RATE), in or before 2009. However, in response to the Report from the Joint Committee on the Human Tissue and Embryos (draft) Bill, the Government subsequently withdrew the proposal to create RATE. The HFEA intends to develop a new medium to long term strategy during the 2008/09 business year. This will set out fresh corporate strategic goals for the future, and will be informed by the legislative changes going through Parliament, and the HFEA's Programme 2010 organisational development work programme.



Current corporate goals (2004/09):

1. Reducing the cost and burden of regulation and ensuring that it is proportionate, targeted and risk-based.
2. Preparing the organisation for transition to the Regulatory Authority for Tissue and Embryos (RATE), and for regulating against the changing demands of new legislation. (The first half of this corporate strategic aim is no longer applicable, but regulating against changing demands is one of the main themes for 2008/09).
3. Being an open organisation, through excellent communications and working in partnership with stakeholders.
4. Working closely with other regulators and with international agencies.
5. Strengthening the process of policy development.
6. Developing an information base which meets the needs of offspring, stakeholders, and the wider regulation and public health functions.
7. Supporting the development of research in assisted conception, and its application.
8. Developing an organisation which will fulfil these goals, supported by strong corporate governance.
2. Quarters 1 and 2: Support the Department of Health to establish RATE, working closely with the HTA and maintaining strong relationships with stakeholders to ensure a smooth transition.
3. Subsequently, following the decision in October 2007 not to proceed with RATE, objective 2 was reworded as follows:
4. Quarters 3 and 4: Work with the HTA to promote further joint working, in the interests of more streamlined regulation and support services.
5. Promote public understanding of and confidence in research on assisted conception and embryos through proportionate effective regulation and transparent policy making.
6. Develop policies and methods to support effective regulation, ensuring evaluation and amendment as appropriate.
7. Improve the range of reliable, meaningful information and advice available to patients, donors, offspring and the public on the performance of services regulated.
8. Maintain robust corporate governance, financial and staff management to increase cost effectiveness.
9. Implement the HFEA's Diversity Strategy and ensure diversity is addressed in all our functions.
10. Ensure that the organisation recruits and retains staff with the right skills and knowledge to achieve its objectives, through a robust organisational development strategy, focused on successful change management.

Meeting Key Challenges

During the past year, the HFEA worked to deliver its 2007/08 business plan, and to drive improvements.

The HFEA's objectives for 2007/08 were:

1. Ensuring patient safety through effective, proportionate, risk-based regulation, and implementing the requirements of the EUTCD to IVF and donor insemination clinics and services new to regulation.

These objectives, and the HFEA's usual range of core operational work, were delivered in the following ways during 2007/08:

Regulation, Inspection and Licensing

The HFEA delivered its annual programme of regulation, inspection and licensing activity, including associated regulatory action. Improvements included further streamlining of



the licensing process for research and treatment through the introduction of risk-based inspection, using a revised risk assessment tool. Person Responsible (PR) assessments were carried out and feedback was obtained from PRs after inspections. A new PR assessment procedure was also implemented for research establishments.

Licensing activity included continued prompt and efficient processing of licence applications and renewals, including those for Preimplantation Genetic Diagnosis (PGD) and the import/export of gametes. Clinics that were newly regulated under the EU Tissue and Cells Directive (EUTCD) were successfully integrated into regulatory activity and all IVF clinics were relicensed under the new legislation. The EUTCD requirements brought a considerable additional workload for both the HFEA and for clinics already regulated under the HFE Act. Whilst additional inspectors were brought in to regulated those clinics new to regulation, for existing clinics, the extra work was managed within our existing staffing levels and resources. However, there was an impact on certain performance indicators as can be seen in the table on page 16.

Preparatory work was started relating to the potential future increase in regulatory powers arising from the Regulatory Enforcement and Sanctions Bill, further work on which is planned for 2008/09. The HFEA implemented electronic incident reporting by licensed clinics, and published a review of the findings of research inspections.

staff also advised and trained the Hong Kong Government on how to establish a regulator for IVF.

Throughout the year, the HFEA engaged with a wide range of stakeholders. This was accomplished in a number of ways. Views were gathered through discussions with the Licensed Centres Panel, meetings with Patient and Donor Organisations, and gaining patients' views through the Fertility Views on-line panel. Further information was gathered by working with other regulators such as the Healthcare Commission, and professional bodies including the British Fertility Society, Royal College of Obstetricians and Gynaecologists, the Association of Clinical Embryologists, the Royal College of Nursing's Fertility Nurses Group, the British Infertility Counselling Association and the Project Group on Assisted Reproduction.

HFEA staff provided support to the Human Tissue Authority (HTA) for Human Resources, Finance, IT and Legal Services. The HFEA also worked together with the HTA and the Department of Health on three project groups which were established to prepare for the anticipated formation of the Regulatory Authority for Tissues and Embryos (RATE). In response to the Report from the Joint Committee on the Human Tissue and Embryos (draft) Bill, the Government withdrew the proposal to create RATE in October 2007.

Joint Working and Stakeholder Involvement

The HFEA also continued to work with other regulators, including joint working with the Healthcare Commission, and participation in the European Union project on regulation (known as EUSTITE: European Union Standards and Training in the Inspection of Tissue Establishments). During the year, the HFEA continued to work with the International Society for Stem Cell Research on current and future research developments. HFEA



Policy Development

A review of the HFEA's policy on the use of human eggs in research was completed and published. The HFEA initiated a widespread public dialogue on the use of hybrid embryos in research, with support from Sciencewise, a government programme funded by the Department of Innovation, Universities and Skills. A public report on this was subsequently produced in October 2007. This work led to a policy decision on how the HFEA should approach the licensing of interspecies embryos for research.

In addition to the consultation to assess public and scientific opinion on the use of hybrids in research, a range of other policy work was carried out. An HFEA policy was developed on reducing multiple births in assisted reproduction, in partnership with the sector.

A new policy to improve witnessing procedures in embryology laboratories was implemented. Work was commenced in preparation for the Review of the 1990 Human Fertilisation and Embryology Act, providing advice and starting to plan ahead for changes which will be implemented in the 2008/09 business year and beyond. This included contributing to the work of the Joint Parliamentary Scrutiny Committee on the draft Bill.

The 7th edition of the Code of Practice was issued for licensed clinics and research establishments, and a web-based interactive edition was published, to increase accessibility.

The HFEA's annual horizon scanning activities identified priority areas of scientific embryology research and practice. A report summarising the horizon scanning issues identified, prioritised and considered in 2005 and 2006 was published.

In accordance with the Government's Better Regulation agenda, the HFEA developed a model process for conducting impact assessments (including the assessment of potential equalities impacts for all new major activities and projects), and for costing the implications of simplification plans.

Information and Communications

The HFEA published a range of communications materials, in print and on the web, including information for patients such as two updates of the "Find a Clinic" facility on the web site, the HFEA Guide to Infertility and a Long-Term Data Analysis for 1991/06. The HFEA also published its first report on licensed research.

HFEA staff provided training and ongoing direct support to licensed clinics in the use of electronic data interchange (EDI) to improve the accuracy of data submitted. The HFEA also validated the data to be used in the Interactive Guide, and maintained and amended the format of the interactive Code of Practice for clinics.

The HFEA responded to an increasing number of requests made under the Freedom of Information Act 2000. The organisation also responded to Opening the Register requests and a range of other enquiries from patients and the public.

Financial Management and Corporate Governance

Throughout the year our financial management processes continued to ensure sound budgeting, compliance, invoicing and accounting. The HFEA complied with all relevant accounting standards and produced and laid its Annual Report and Accounts for the 2006/07 financial year prior to the summer recess in 2007.

The HFEA successfully delivered against its targets set out by the Department of Health's (DH) Arms Length Body (ALB) Review programme. This programme was designed to generate savings across the whole ALB sector for the DH by the end of 2007/08. In 2005/06, the HFEA drew down over £6 million in Grant-in-Aid, covering both revenue and capital expenditure. For the financial year ending 31 March 2008, the HFEA

drew down £2.5 million in Grant-in-Aid. Total expenditure in 2005/06 was over £11 million and in 2007/08 was £7.9 million. All returns to the Department of Health were completed on time. Improved information on income was achieved, through the implementation of EDI. All purchasing decisions followed appropriate tendering procedures, to ensure that good value for money was obtained in procurement.

Existing risk management procedures were further developed, with the introduction of operational risk logs by departments, to increase awareness and anticipation of risk at operational level. Ongoing support for the Authority's procedures and its processes for corporate governance included a review of the Authority's business management and decision-making framework, and implementation of a new Committee structure to meet current needs. The HFEA also finalised a number of outstanding legal actions.

The HFEA also reviewed its complaints procedure during the year, to make it simpler, clearer, and more user friendly. The presentation and positioning of the procedure on the website was much improved, and a form is now provided to assist potential complainants in outlining the details of their complaint so that the matter can be investigated more efficiently.

Key Human Resources metrics were monitored to enable proactive and well informed staff management, including sickness and absence rates, recruitment, staff turnover and reasons for leaving.

The HFEA continued to ensure effective performance management through annual staff Performance and Development Plans (PDPs) and 6 month reviews of progress against objectives. We implemented a competency framework approach for use in PDPs, and for recruitment purposes. Organisational training priorities were agreed to ensure staff and Members have the right skills and knowledge to enable them to deliver the organisation's business. We continued to ensure our office environment was appropriate to support staff in the effective delivery of business.

During the year we also examined our internal processes, including those for recording and reporting performance information across a range of activities. In the course of this exercise, we identified an error in the number of incidents at clinics that had been recorded. As a result, incorrect figures had been published in the previous two annual reports. The numbers of incidents reported in the annual reports for 2005/06 and 2006/07 were significantly different than was actually the case. In 2005/06 we reported that there had been 97 incidents; the actual number was 140. In 2006/07 we reported 224 incidents; the actual number was 173. Our recording systems have now been changed so that incident figures can be accurately reported in the future.

Diversity

Consideration of diversity issues was built into planning through the introduction of an Equalities Impact Screening and Assessment tool, which is now applied to all new major projects and activities. Training in diversity issues was also provided to staff and Authority members.

A Diversity Update was introduced for the sector, to enable diversity issues and best practice to be shared, including information for Clinics about equalities legislation and its implications.

Links have also been made with media targeted at minority audiences, for example to increase the representation of ethnic minorities in the Fertility Views panel membership.

Financial Review

The financial results of the HFEA are included in the accounts on pages 69-88 and show that the HFEA's net expenditure for the financial year was £2,599,724 (2006/07 £3,033,318). This expenditure was financed in part by Grant-in-Aid towards resource expenditure of £2,399,000 (2006/07 £1,650,422) and £87,000 towards purchase of fixed assets (2006/07 £88,578). Income from



fees charged to clinics was £5,212,804 (2006/07 £4,330,140). Capital expenditure was £238,948 (2006/07 £88,578).

2007/08 saw the HFEA commence regulation under the new requirements of the EUTCD. The cost of regulating a larger number and wider span of clinics was in part offset by more efficient and risk-based inspection practices. Overall, fee levels have increased, reflecting both the increased number of clinics regulated by the HFEA and impact of the Electronic Data Interchange (EDI). The first full year of the EDI in 2007/08 has resulted in clinics reporting their treatments faster, as data is transmitted electronically instead of paper forms being sent to the HFEA office.

The HFEA reviewed the level of provision against potential legal costs and following advice made an adjustment of £78,000.

The HFEA commenced a capital programme of expenditure in March 2008 to enable 'server virtualisation', which provides a more stable and flexible data storage environment. This was in part funded by fee income. The programme will be completed in 2008/09.

Staff Resources

The HFEA employed an average of 90 employees over 2007/08 (94 in 2006/07). Following the Arms Length Body Review, targeted staff reductions were successfully achieved by the HFEA and the level of staff resources required in 2007/08 was stable. 2008/09 is likely to show an increased resourcing requirement as the HFEA enters a change programme and the HFE Bill progresses through Parliament.

Employee Consultation

The HFEA Staff Forum continued to play an important role during the year, across a range of operational processes and policy at the HFEA. The Staff Forum was also actively involved in issues relating to staff welfare. The Staff Forum exists to supplement the current arrangements the

organisation has for regular communication with staff, such as all staff meetings, team meetings, one to one supervision, intranet, programme boards/working groups and focus groups.

The Forum's focus is to encourage the development of an environment in which ideas can be shared and created. It acts as a vehicle for canvassing staff opinion on business issues and as a communication channel through which issues that are of concern to staff can be discussed. Topics discussed included equality and diversity strategy, HR policy reviews, revision and improvement of a competencies framework and changes to the PDP process, internal communications, environmental issues, and key aspects of staff welfare and satisfaction.

In addition, written briefing documents have been introduced during the year to ensure that staff are kept fully involved and informed, particularly those staff who are not solely office based, such as Inspectors, and to ensure greater consistency in internal communications across the organisation.

Pensions

Pension benefits are provided by the Principal Civil Service Pension Scheme (PCSPS). The HFEA recognises the contributions payable for the year. Full details of the pension scheme are included in the Remuneration Report on pages 47-55.

Equality & Diversity

The HFEA is committed to equality for all employees and job applicants in respect of employment, career development and remuneration. This is regardless of gender, marital status, race, ethnic or national origin, religion or belief, sexual orientation or disability, fixed term or part time status.

It is recognised that a diverse workforce is of benefit to the organisation, bringing different skills and perspectives, and ensures that we think more widely and creatively in our work, continuing to challenge ourselves to meet a greater breadth of needs.

We have a diversity strategy and action plan in place, which is a public statement of our commitment to diversity and how we address it within the HFEA. We will continue to report on this policy and publicise our progress.

We have provided Equality and Impact Assessment training to all those who are involved in creating policy within the HFEA. A training programme on diversity awareness was delivered, and this will be built upon with a new training package available to all staff electronically.

HR closely monitors and reviews access to jobs, promotion, training and reward and has commenced a focused equal pay review to address any potential areas of concern.

Disabled Employees

In 2007/08 the HFEA published an annual progress report on the disability aspects of the equality scheme, and achieved ✓✓ Positive about Disabled People disability symbol status. We will continue to build on this.

The HFEA has a specific policy to invite any candidate with a disability who meets essential criteria to interview. Support is provided for all staff who have, or develop, a disability including reasonable adjustments to the workplace or work processes and advice through the Occupational Health Service.

Social, Community and Environmental Issues

The HFEA will be finalising a new Accommodation Strategy in 2008, including a Sustainable Development Action Plan. The HFEA recycles glass and plastic bottles, cans, paper and cardboard, and toner cartridges. The organisation uses plumbed-in water coolers instead of bottled water. There are a range of employee benefits in place to support a positive work-life balance, including access to Familylife Solutions and childcare vouchers, support for staff who wish

to stop smoking, and access to the Government backed 'Cyclescheme' discount, to promote cycling to work.

Accounts Direction

The statement of accounts which follows is prepared in a form directed by the Secretary of State for Health dated 18th June 2007, in accordance with section 6 of the Human Fertilisation and Embryology Act 1990.

Performance Indicators – Achievement 2007/08

Performance against 2007/08 indicators:	Target 2007/08	Achieved 2007/08
A. Regulation		
No. of random unannounced inspections carried out in the year	4	4
Reports resulting from inspection of clinics available to clinic within 28 working days of the inspection date	90%	75.9% ¹
Reports resulting from research inspections available to research establishment within 28 working days	90%	76.15% ²
New licence applications processed within 4 months of receipt	90%	90.75%
Research licence applications processed within 3 months of receipt of complete application & peer review	100%	100%
Reduction in items of information required from clinics for inspections	Further 10% reduction	Achieved
B. Communication and Information		
Patient/public enquiries replied to within 3 working days	95%	67% ³
Number of 'page views' of 'For Patients' section of website	5% increase	49% increase ⁴
Number of 'page views' of Find a Clinic function on website	5% increase	15% increase
Number of Authority meetings held in public during the year	3	3
Number of stakeholder events	8	30 ⁵
Freedom of information (FOI) requests dealt with within 20 working days	100%	99.4%
Publication of finalised Licence Committee decisions on the website	90% within 20 working days	77.5% ⁶
C. Corporate		
Invoices paid within 30 days	95%	97.25%
Debts collected within 60 days	85%	82.5% ⁷
Monthly billings of clinics achieved in three weeks	95%	98.5%

Performance against 2007/08 indicators:	Target 2007/08	Achieved 2007/08
D. Diversity		
Initial EIA screening completed for all major new policies or projects	95%	100%
Full EIA completed for all major policies or projects identified as requiring additional assessment	95%	(None required)
Develop self assessment and pre-inspection questionnaires, and provide guidance to clinic staff in their use	75% (of clinics)	100%
E. Arm's Length Bodies (ALB) Targets		
Reduce revenue costs	£2.109m Grant-in-Aid	Achieved
Reduce full-time equivalents to 82.1 by March 2007 and then maintain this reduction	82.1	82.15

1. There were various additional work pressures in the year, particularly the implementation of the EUTCD and a very high number of inspections in the final quarter. These affected several performance targets.
2. See footnote 1 above.
3. Better information on the HFEA's website means that staff now receive only the more complex enquiries, which in turn means response times are necessarily longer. In addition, staff vacancies during the year have meant there were fewer staff available to deal with these enquiries. These vacancies have now been filled.
4. This higher than expected increase reflects improvements to the website.
5. There were various additional stakeholder consultation events in connection with policy development work on the use of hybrids in research, and on multiple births.
6. See footnote 1 above. In the final two quarters of the year, however, delivery had returned to 100% for this target.
7. By the final quarter, this indicator was on target. There were some initial issues with newly regulated clinics, which were subsequently resolved.

Other performance highlights of the year

Clinics and research establishments inspected	119 (compared to 111 in 2006/07)
New licence applications processed	43
Licence renewals processed	49
Applications for Preimplantation Genetic Diagnosis (PGD) processed	17 (compared to 12 in 2006/07)
Services new to regulation integrated into regulatory activity under the European Union Tissue and Cells Directive (EUTCD)	35
Clinics relicensed under the EUTCD	116
Research inspection reports published on the HFEA website	11
Licensed Centres Panel meetings held	3
Meetings held with Patient Organisations	3
Fertility Views Panel surveys conducted	1
Public and stakeholder consultation meetings on multiple births and single embryo transfer	5
Freedom of Information requests dealt with	472 (compared to 152 in 2006/07)
Opening the Register requests dealt with	65 (compared to 149 in 2006/07)
Enquiries responded to under the Data Protection Act	16
Enquiries responded to under the Environmental Information Regulations	1
Number of Authority meetings held (should be after the figure 9 on the right)	9 (including 3 open to the public)
Phone and email enquiries dealt with from patients and the general public	18,118 (compared to 24,926 in 2006/07 – a reduction reflecting the trend towards increased web-based handling of enquiries)
Phone and email enquiries from clinics and research establishments dealt with by inspectors	4,482
Number of visits to the HFEA website	449,048

Future Developments

The key objectives for delivery in 2008/09 are:

- A.** Continuously improve the effectiveness of regulation, information to support patient choice, and the policy framework.
- B.** Be ready to put the new HFE Act into effect in keeping with the Government's intentions by: reviewing and updating the Code of Practice; redesigning the functions of the HFEA; and updating processes and procedures.
- C.** Raise the quality of the information the HFEA makes available to each of its stakeholders, including patients, the public, clinics, donors and donor-conceived individuals.
- D.** Ensure that the HFEA is able to offer the best guidance on existing and new infertility treatments through evidence based decision making, monitoring existing research, and horizon scanning for scientific developments.

Risks and Uncertainties as at June 2008

The HFEA operates within a fast-changing, dynamic environment which inevitably increases its exposure to risk as it is a small, tightly-focused organisation. Many of its staff are highly skilled and specialised. This creates a challenge both in terms of recruitment and retention. There is limited flexibility to move staff within the organisation which makes it increasingly difficult to re-prioritise tasks during the life of the business plan.

The main risks and uncertainties for the present business year (2008/09) are summarised in the table below:

Risk	Mitigating Factors and Actions
Organisational delivery:	
The HFEA continues to have a challenging business plan in place for 2008/09. The organisation is also looking to deliver a major change programme, alongside delivery of continuing business as usual. All of this must be accomplished against a backdrop of recent and forthcoming new legislation, continued stringent requirements from our sponsorship body, the Department of Health, the ongoing implementation of the European Union Tissue and Cells Directive (EUTCD), and the potential for increased volumes of information requests or legal challenges relating to new arrangements. This places pressure on all of HFEA's resources.	<p>Advanced planning to assess resource needs.</p> <p>Formal project management processes.</p> <p>External advisors to assist with the increased volume of inspections resulting from newly regulated services under the EUTCD.</p> <p>Clinical governance process to handle incident reporting and the production of alerts.</p> <p>System of audit and risk-based inspections to focus resources appropriately.</p> <p>Work to develop a clear policy position on information for researchers.</p> <p>Project to examine a range of consent issues.</p> <p>Panel of legal firms appointed, with specific litigation and public law expertise.</p> <p>A programme of legal training planned for Authority Members.</p> <p>HFEA's resources managed so as to handle the potentially high costs of legal/defensive actions, in dialogue with the Department of Health.</p>

Risk	Mitigating Factors and Actions
New and Changing Legislation:	
<p>That the HFEA fails to meet the minimum requirements for applying for new statutory powers available as a result of the Regulatory Enforcement and Sanctions (RES) Bill, or that the HFEA has insufficient resources to bring itself up to the required standard, or to operate any new powers applied for.</p>	<p>Thorough consideration of the RES Bill is being undertaken, with a view to deciding which powers the HFEA should apply for, and to scope out the implications.</p> <p>Communications with the sector to raise awareness and ensure good levels of compliance.</p>
<p>That the HFEA experiences difficulties in balancing its approach to Better Regulation (which aims to decrease the burden of regulation for licensed clinics and research establishments) with its duties as a regulator.</p>	<p>More principles-based approach to regulation to be introduced through the planned new edition of the Code of Practice.</p> <p>Good communications with licensed clinics and research establishments on regulatory requirements and the ways in which the regulatory burden is being reduced.</p>
<p>That the additional workload associated with implementing the HFE Bill is not properly resourced, and that it is subject to expansion, overloading the business plan and jeopardising other work.</p>	<p>Detailed early planning and full scoping.</p> <p>Thorough business case produced, detailing all associated resourcing needs.</p> <p>Ongoing dialogue with the Department of Health to agree additional resourcing.</p>
Regulation and Policy	
<p>That the HFEA policy on multiple births is not properly understood or is not adopted in practice by one or more key audiences.</p>	<p>Work with licensed clinics and partner bodies (professional and patient organisations) on the national strategy for multiple births.</p> <p>Communications campaign in 2008/09.</p>
Corporate Knowledge Management	
<p>Because of the high pressure, high change context in which the HFEA is working, that staff turnover increases and corporate knowledge is lost, with a knock-on effect on staff morale.</p>	<p>Work to ensure procedures and processes are well documented so that existing corporate knowledge is captured.</p> <p>Retention of staff through offering excellent employer practices and conditions of service.</p>
<p>That the internal change management work (Programme 2010) leads to an increase in turnover and a loss of existing working knowledge and practices, absorbs disproportionate resources, and diverts attention away from delivery of business.</p>	<p>Continued focus on internal communications and active staff engagement as staff involvement is integral to the change management work.</p> <p>External expertise and resources have been brought in to avoid overloading staff and detracting from the delivery of core business.</p>
<p>That recent changes in Authority membership and the position of Chair, coupled with the end of six Members' terms of office later in the business year, result in a lack of top-level continuity, and loss of key corporate knowledge.</p>	<p>Induction and acclimatisation arrangements in place.</p> <p>Organisational development work is being undertaken to improve decision-making and governance.</p>

Disclosure of Information to HFEA Auditors

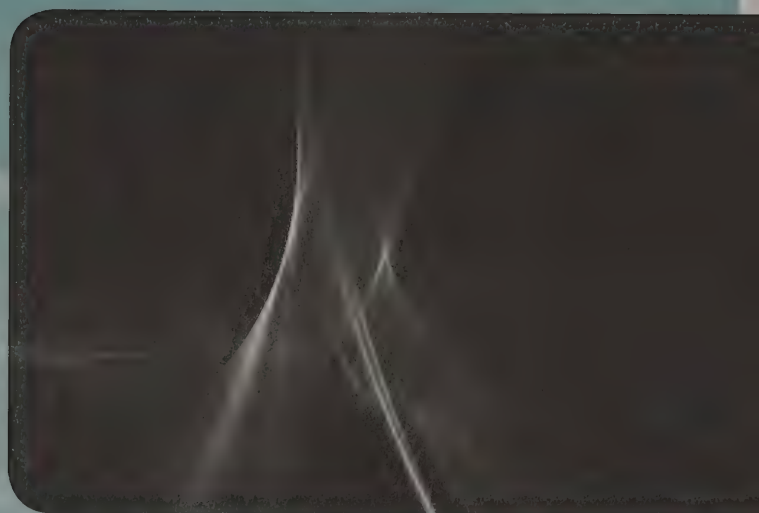
The Interim Chief Executive of the HFEA has been designated as the Accounting Officer for the Authority. The Accounting Officer has taken all the steps that are necessary to make himself aware of any relevant audit information and to establish that the HFEA's auditors (the NAO) are aware of that information. So far as the Accounting Officer is aware, there is no relevant audit information of which the NAO is unaware.



Mr Alan Doran CB

Interim Chief Executive

10 June 2008



03 Appendices



Appendix 1

Standing Committee Membership as at 31 March 2008:

Resources Committee	Regulation Committee	Audit Committee
<ul style="list-style-type: none">• Chair: Ruth Fasht OBE• Anna Carragher• Christopher Barratt• Clare Brown• Rebekah Dundas• Ros Gardner (co-opted member)	<ul style="list-style-type: none">• Chair: Emily Jackson• William Ledger• Clare Brown• Roger Neuberg• Walter Merricks CBE• Emily Jackson• Maybeth Jamieson• Jennifer Hunt• Hossam Abdalla• Anna Carragher	<ul style="list-style-type: none">• Chair: Sally Cheshire• Jennifer Hunt• Emily Jackson• Clare Brown• Roger Neuberg• Kim Hayes (DH observer)
Strategy Committee	Information & Communications Committee	
<ul style="list-style-type: none">• Chair: Walter Merricks CBE• Sally Cheshire• Sharmila Nebhrajani• Ruth Fasht OBE	<ul style="list-style-type: none">• Chair: Anna Carragher• Walter Merricks CBE• William Ledger• Hossam Abdalla• Rebekah Dundas• Kim Hayes (DH observer)	

Scientific & Clinical Advances Advisory Group	Ethics & Law Advisory Group
<ul style="list-style-type: none"> • Chair: Neva Haites OBE • Roger Neuberg • Christopher Barratt • Clare Brown • Maybeth Jamieson • Lord (Richard) Harries of Pentregarth • Ted Webb (DH observer) • Peter Braude (co-opted member) • Robin Lovell Badge (co-opted member) • Melanie Davies (co-opted member) • Richard Gardner (co-opted member) • Daniel Brison (co-opted member) • David Barlow (co-opted member) • Lorraine Young (co-opted member) 	<ul style="list-style-type: none"> • Chair: Lord (Richard) Harries of Pentregarth • Neva Haites OBE • Jennifer Hunt • Emily Jackson • David Archard • Hossam Abdalla • Sally Cheshire • Anna Carragher • Sue Price • Martin Richards (co-opted member)

Appointment Summary of Authority Members as at 31 March 2008:

Member	Category	Expertise	Date Appointment commenced	Re-appointment dates (if applicable)	Date appointed ends
Shirley Harrison (Chair ⁸)	Lay	Marketing/PR	01.01.07		Resigned on 31.10.07
Walter Merricks CBE (Interim Chair)	Lay	Finance and Patient	02.12.02 (Interim Chair 1.11.07 –31.03.08)	01.12.05 2nd	30.11.08
Hossam Abdalla	Professional	Clinical	01.10.04	30.09.07 2nd	29.09.10
David Archard	Lay	Philosophy	01.11.05		31.10.08
Christopher Barratt	Professional	Andrologist	15.01.02	07.11.04 2nd 07.11.07 3rd	06.11.09
Clare Brown	Lay	Patient	02.12.02	01.12.05 2nd	30.11.08
Anna Carragher	Lay	Media	07.11.06		06.11.09
Sally Cheshire	Lay	Accountancy	07.11.06		06.11.09
Rebekah Dundas	Lay	Patient Rep	01.01.07		31.12.10
Ruth Fasht OBE	Lay	Children and Family Welfare	01.11.05		31.10.08
Neva Haites OBE	Professional	Clinical Genetics	02.12.02	01.11.05 2nd	30.11.08
Lord (Richard) Harries of Pentregarth	Lay	Moral theologian	06.11.03	(01.09.06-31.12.06 as interim Chair) 01.01.07 2nd	31.12.09

8. Professor Lisa Jardine CBE took up the post of Chair on 01.04.08

Member	Category	Expertise	Date Appointment commenced	Re-appointment dates (if applicable)	Date appointment ends
Jennifer Hunt	Professional	Counsellor	06.11.03	07.11.06 2nd	06.11.09
Emily Jackson	Lay	Healthcare and Law	01.06.03	01.12.05	30.11.08
Maybeth Jamieson	Professional	Embryology	02.12.02	01.12.05 2nd	30.11.08
William Ledger	Professional	Clinical	07.11.06		06.11.09
Sharmila Nebhrajani (Deputy Chair)	Lay	Management, accountant and media	07.11.98	06.11.01 2nd 07.11.04 (extended 1 year to 7.11.05) 3rd	31.10.08
Roger Neuberg	Professional	Clinical	07.11.06		06.11.09
Susan Price	Professional	Clinical Genetics	01.02.06		31.01.09

Licence Committee Members as at 31 March 2008:

TEAM A	TEAM B	TEAM C	TEAM R (Research)
Chair: Clare Brown (lay)	Chair: Anna Carragher (lay)	Chair: Walter Merricks CBE (lay)	Chair: Emily Jackson (lay)
Ruth Fasht OBE (lay)	Rebekah Dundas (lay)	Jennifer Hunt (counsellor)	Clare Brown (lay)
Sue Price (clinical geneticist)	Lord (Richard) Harries of Pentregarth (lay)	David Archard (lay)	Lord (Richard) Harries of Pentregarth (lay)
Christopher Barratt (andrologist)	Emily Jackson (lay)	Sally Cheshire (lay)	Maybeth Jamieson (embryologist)
Roger Neuberg (clinician)	Maybeth Jamieson (embryologist)	Neva Haites OBE (geneticist)	Neva Haites OBE (geneticist)
	William Ledger (clinician)	Hossam Abdalla (clinician)	

Horizon Scanning Expert Panel Membership as at 31 March 2008:

Name	From
Professor Twink Allen	University of Cambridge, UK
Professor Peter Andrews	University of Sheffield, UK
Professor David Barlow	University of Glasgow, UK
Professor Keith Campbell	University of Nottingham, UK
Professor John Carroll	University College London, UK
Dr Jacques Cohen	Institute for Reproductive Medicine and Science of Saint Barnabas, USA
Professor Alan Decherney	National Institutes of Health (NIH), USA
Professor Chris De Jonge	University of Minnesota, USA
Professor Paul Devroey	Free University of Brussels, Belgium
Professor David Edgar	University of Liverpool, UK
Sir Professor Martin Evans	Cardiff University, UK
Professor Hans Evers	Academic Hospital Maastricht, The Netherlands
Dr Joyce Harper	University College London, UK
Professor Stephen Hillier	University of Edinburgh, UK
Professor Outi Hovatta	Karolinska Institute, Sweden
Dr Mark Hughes	Genesis Genetics Institute, Detroit, USA
Professor Martin Johnson	University of Cambridge, UK
Professor Gab Kovacs	Monash IVF, Australia
Professor Henry Leese	University of York, UK
Dr Norio Nakatsuji	Kyoto University, Japan
Professor Andre Van Steirteghem	University Hospital Brussels, Belgium
Professor Alan Trounson	California Institute for Regenerative Medicine, USA
Dr Maureen Wood	Aberdeen Fertility Clinic, UK
Professor Stéphane Ville	Université Louis Pasteur, Strasbourg, France

Appendix 2

Centres licensed by the HFEA as at 31 March 2008:

T = Treatment

S = Storage

R = Research

Centre number	Name	Licences held
0004	Ninewells Hospital	TSR
0005	Peninsular Centre for Reproductive Medicine	TS
0006	The Lister Fertility Clinic	TSR
0007	Hewitt Centre for Reproductive Medicine	TSR
0008	Midland Fertility Services	TS
0011	Louis Hughes	S
0013	Centre for Reproductive Medicine, Coventry	TSR
0015	Sussex Downs Fertility Centre	TS
0016	CARE Northampton	TS
0017	Newcastle Fertility Centre at Life	TSR
0019	Aberdeen Fertility Centre	TS
0021	Hull IVF Unit	TS
0026	BMI Priory Hospital	TS
0030	Herts and Essex Fertility Centre	TS
0031	Hartlepool General Hospital	TS
0032	Southmead Hospital	TS
0033	Manchester Fertility Services Ltd	TSR
0035	Oxford Fertility Unit	TSR
0037	Glasgow Royal Infirmary	TSR
0044	UCH London	TS
0049	IVF Wales	TSR
0051	The Rosie Hospital	S
0052	Clarendon Wing - Leeds	TSR
0055	The James Cook University Hospital	TS
0056	Cleveland Gynaecology and Fertility Centre	TS
0057	Wessex Fertility Limited	TS
0059	London Women's Clinic, Swansea	TS

Centre number	Name	Licences held
0061	CARE Sheffield	TS
0062	University Of York	R
0063	Assisted Conception Unit, St James' University Hospital - Leeds	TS
0064	The Chiltern Hospital Fertility Services Unit	TS
0067	St Mary's Hospital	TSR
0068	Leicester Fertility Centre	TS
0070	The Bridge Centre	TS
0075	London Women's Clinic, Darlington	TS
0076	NURTURE	TSR
0077	Regional Fertility Centre, Belfast	TS
0078	IVF Hammersmith	TSR
0080	Andrology Unit, Hammersmith Hospital	S
0086	BMI Chelsfield Park ACU	TS
0088	London Fertility Centre	TS
0094	The Centre for Reproductive Medicine	TS
0096	Sunderland Fertility Centre	TS
0098	Lanarkshire Acute Hospital NHS Trust	TS
0100	Bourn Hall Clinic	TS
0101	CARE Nottingham	TS
0102	Guys Hospital	TSR
0105	London Women's Clinic	TS
0109	Assisted Conception Unit, King's College Hospital	TS
0115	Glasgow Nuffield Hospital	TS
0117	Queen Mary's Hospital	T
0119	Birmingham Women's Hospital	TSR
0133	The Winterbourne Hospital	TS
0138	North East London Fertility Services	TS
0139	Bath Assisted Conception Clinic	TS
0143	London Female And Male Fertility Centre	TS
0144	The Woking Nuffield Hospital	TS
0148	Shropshire and Mid-Wales Fertility Centre	TS
0149	Derby City General Hospital	TS
0151	Gloucestershire Hospitals NHS Trust	S

Centre number	Name	Licences held
0153	Homerton University Hospital	TS
0157	Assisted Reproduction and Gynaecology Centre	TS
0158	Chelsea & Westminster Hospital	TSR
0159	Royal Surrey County Hospital	S
0161	BMI The Chaucer Hospital	TS
0162	Queens Medical Centre Fertility Unit	TS
0163	Shirley Oaks Hospital	TS
0165	Brentwood Fertility Centre	TS
0167	Reproductive Medicine Unit	TS
0168	Bishop Auckland General Hospital	TS
0170	Centre for Assisted Reproduction, Gateshead	TS
0171	Bridge Centre Cryoservices	S
0175	University of Manchester	R
0178	The Fertility Unit, Peterborough District Hospital	TS
0179	South West Centre for Reproductive Medicine	TS
0184	Burton Hospitals NHS Trust	TS
0185	CARE Manchester	TS
0186	The Harley Street Fertility Centre	TS
0187	The Harley Street Clinic	T
0188	Isis Fertility Centre	TS
0190	Subfertility Unit, James Paget Healthcare NHS Trust	S
0191	Section of Reproductive and Developmental Medicine	R
0196	Centre for Reproductive Medicine and Fertility, Sheffield	TS
0197	Salisbury Fertility Centre	TS
0198	St Jude's Women's Hospital	TS
0199	CRM London	TS
0200	Origin Fertility Care	TS
0201	Edinburgh Assisted Conception Unit	TS
0202	Roslin Cells Limited	R
0208	South East Fertility Clinic	TS
0209	Institute of Biomedical Research	R
0245	Human Genetics & Embryology Laboratories	R
0246	University of Cambridge	R



Centre number	Name	Licences held
0249	Institute of Reproductive and Development Biology	R
0250	Glasgow Centre for Reproductive Medicine	TS
0251	Centre for Human Development, Stem Cells and Regeneration/ Division of Human Genetics	R
0252	Wellcome Trust Centre for Stem Cell Research University College Cambridge	R
0254	The Agora Gynaecology and Fertility Centre	TS
0255	Reproductive Medicine Unit Department Of Obstetrics And Gynaecology	T
0256	Luton And Dunstable NHS Trust Hospital	T
0258	The Whittington Hospital Fertility Unit	T
0259	Epsom And St Helier NHS Trust	T
0260	Torbay Hospital	T
0261	Good Hope Hospital NHS Trust	T
0262	Stockport NHS Foundation Trust	T
0265	Princess Of Wales Hospital	T
0267	Solihull Hospital	T
0268	Sandwell and West Birmingham Hospitals NHS Trust	T
0269	The Royal West Sussex Trust St Richard's Hospital	T
0270	Assisted Conception Unit Queen Mary's Hospital	T
0271	Maternity Department St Mary's Hospital	T
0272	Arrowe Park Fertility Clinic	T
0273	Swansea Reproduction Unit	TS
0274	Ipswich Hospital NHS Trust	T
0275	Dumfries And Galloway Royal Infirmary	T
0276	Reproductive Medicine Clinic	T
0277	Hexham General Hospital	T
0278	Assisted Conception Unit Leigh Infirmary	T
0279	Leighton Hospital	T
0280	Countess Of Chester Hospital	TS
0281	St Mary's Hospital	T
0282	Royal Cornwall Hospital	T
0283	Yeovil District Hospital	T
0284	Spire Bristol Hospital	T
0285	BMI The Hampshire Clinic	T

Centre number	Name	Licences held
0287	Crosshouse Hospital	T
0288	The Royal Bournemouth NHS Foundation Trust	T
0289	North Middlesex Hospital	T
0290	University Hospitals of Morecambe Bay NHS Trust Furness General Hospital	T
0291	Fertility Unit Barking, Havering and Redbridge Hospitals Trust	T
0292	St Mary's Hospital NHS Trust	T
0293	Andrology Solutions	T
0294	Craigavon Area Hospital	T
0295	Bristol Centre for Reproductive Medicine	TS
0296	Centre for Stem Cell Biology & Developmental Genetics	R
0297	Stem Cell Biology Laboratory, Kings College London	R
0298	Women's Health Unit Pontypridd & Rhondda NHS Trust	T
0301	London Women's Clinic, Cardiff	TS
0302	West Middlesex University Hospital	T
0303	Scottish Biomedical	R

Appendix 3

External advisors as at 31 March 2008:

Clinical Advisors

Mr Bernard Bentick

Person Responsible/Consultant
Obstetrician and Gynaecologist
Shropshire and Mid-Wales Fertility Centre

Mr Peter Brinsden

Accredited Consultant/Medical Director
Bourn Hall Clinic

Mr Richard Kennedy

Person Responsible/Clinical Director of
Women's Services
Centre for Reproductive Medicine
University Hospitals Coventry &
Warwickshire NHS Trust

Mr Yacoub Khalaf

Person Responsible/Medical Director
ACU, Guy's & St Thomas' Hospital
NHS Trust

Ms Janet Kirkland

Clinical Inspector
Self employed

Mr Tony Knox

Clinical Inspector
Self employed

Mr Stephen Maguiness

Person Responsible/Consultant
Hull IVF Unit, Hull and East Yorkshire
Women and Children's Hospital
Hull Royal Infirmary

Mr Joseph Enda McVeigh

Person Responsible
Oxford Fertility Unit

Mr Nigel Perks

Clinical Director for Women's and
Children's Services
Queen Elizabeth Hospital NHS Trust

Mr Andrew Riddle

Person Responsible/Consultant
Gynaecologist
The Woking Nuffield Hospital

Mr Robert Sawers

Person Responsible/Clinical Director
BMI Priory Hospital

Professor André Van Steirteghem

Emeritus Professor, Reproductive Medicine
and Genetics
University Hospital
Vrije University, Brussels, Belgium

Scientific Advisors

Dr Virginia Bolton

Consultant Embryologist
Assisted Conception Unit, Guy's & St
Thomas' Hospital NHS Trust

Ms Grace Cunningham

Irish Medicines Board, Dublin
Blood & Tissues Inspector

Dr Simon Fishel

Person Responsible/Managing Director
CARE Fertility Group

Professor Lynn Fraser

Professor of Reproductive Biology
Endocrinology & Research Group
School of Biomedical Sciences
King's College London

Ms Stephanie Gadd

Senior Embryologist
Bath Assisted Conception Clinic

Mr David Gibbon

Principal Embryologist & Business Manager
for Fertility Services
The Cameron Unit, North Tees & Hartlepool
NHS Trust
University Hospital of Hartlepool

Mr Andy Glew

Senior Embryologist/Nominal Licensee
Herts & Essex Fertility Centre

Dr Geraldine Hartshorne

Scientific Director
Centre for Reproductive Medicine
University Hospitals Coventry
& Warwickshire NHS Trust

Mr Stephen Lynch

Person Responsible/Senior Embryologist
BMI The Chaucer Hospital

Mr Bryan Woodward

Embryology Consultant
Self Employed

Counselling Advisors

Dr Olga van den Akker
Professor of Health Psychology
Middlesex University

Ms Jennifer Dunlop

Senior Counsellor
St Mary's Hospital/Manchester Fertility Services

Ms Catherine Grieve

Counsellor
Centre for Reproductive Medicine
University Hospitals Coventry &
Warwickshire NHS Trust

Dr Jim Monach

Mental Health Consultant
Self-employed

Ms Sheila Pike

Senior Counsellor
Assisted Conception Unit, Sheffield
Teaching Hospitals NHS Foundation Trust

Nursing Advisors

Ms Debbie Barber

Lecturer in Specialist Clinical Practice
Oxford Fertility Unit

Ms Eileen Graham

Fertility Services Co-ordinator
Bishop Auckland General Hospital

Sister Helen Kendrew

Nurse Coordinator
Bath Assisted Conception Clinic

Ms Caroline Lewis

Unit Manager
Assisted Conception Services
The Woking Nuffield Hospital

Ms Katherine Mangold

Clinical Lead Nurse for
Gynaecology/Nominal Licensee
Assisted Conception Unit
Chelsea and Westminster Hospital

Ms Fiona Pringle

Clinical Nurse Manager
Oxford Fertility Unit

Appendix 4

Research Centres / Projects licensed by the HFEA between 1 April 2007 and 31 March 2008:

Aberdeen Fertility Centre

- Development of Methods for Oocyte Freezing and Vitrification and Provision of Cryopreserved Oocytes for Cell Nuclear Replacement and Stem Cell Production (R0159)
- Development of Methods for the Vitrification of Human Embryos in Sealed Containers (R0164)

Assisted Conception Service, Glasgow Royal Infirmary

- The Effect of Biomass Reduction on Embryo Development after Biopsy of either One or Two Blastomeres (R0175)

Birmingham Women's Hospital /

- Institute of Biomedical Research
- Human Gamete Interaction and Signalling (R0172 / R0173)

Bourn Hall, Cambridge

- The Disaggregation of Embryos for the Purpose of Deriving Stem Cells from Human Surplus Embryos (R0167)

Cardiff Assisted Reproduction Unit

- Investigation into the Role of Sperm PLC- Zeta in Human Oocyte Activation (R0161)

Centre for Assisted Reproduction, Coventry

- Indicators of Oocyte and Embryo Development (R0155)

Centre at LIFE, Newcastle-upon-Tyne

- Epigenetic Studies of Preimplantation Embryos and Derived Stem Cells (R0145)
- Derivation of Human Embryonic Stem Cell Lines using Nuclear Transfer and Parthenogenically Activated Oocytes (R0152)
- Mitochondrial DNA Disorders: Is there a way to prevent transmission? (R0153)

Centre for Stem Cell Biology, University of Sheffield

- Optimisation of Human Embryonic Stem Cell Derivation and the Development of Treatments for Degenerative Diseases (R0115)

Clarendon Wing, Leeds General Infirmary

- Maturation of Fertilisation of Human Eggs in Vitro (R0104)

Guy's Hospital, London

- Improving Methods for Biopsy and Preimplantation Diagnosis of Inherited Genetic Disease of Human Preimplantation Embryos (R0075)
- Correlation of Embryo Morphology with Ability to Generate Embryonic Stem Cell Lines and Subsequent Growth Differentiative Characteristics (R0133)

Human Genetics and Embryology Laboratories, University College Hospital, London

- The Development of Novel Preimplantation Genetic Diagnosis (PGD) Procedures and the Study of Early Human Development (R0113)

King's College London, Stem cell Biology Laboratory Wolfson Centre for Age-Related Disease

- Generation of Disease-Specific Human Embryonic Stem Cell Lines by Somatic Cell Nuclear Transfer (R0180)

Lister Hospital, London

- Analysis of the Impact of Human Embryo Mosaicism on the Reliability of Pre-implantation Genetics Screening (PGS) (R0163)

London Fertility Centre

- Analysis of Chromosomes in Human Preimplantation Embryos using FISH and CGH (R0169)

Ninewells Hospital, Dundee

- Studies of Embryo Development and Metabolism (R0154)

NURTURE, Nottingham

- Evaluation of Cardio Myocytes Derived from Embryonic Stem Cells as a Means to Characterise Receptor/Channel Expression in Human Tissue (R0141)

Oxford Fertility Unit

- Development of a Model to Study Implantation in the Human (R0111)
- To Derive Human Embryonic Stem Cells and Trophoblast Cell Lines (R0143)
- To Develop Pre-implantation Genetic Diagnosis (PGD) for Mitochondrial DNA Disease (R0149)

Reproductive Genetics Institute, London

- Investigation of Major Histocompatibility Complex Products and Soluble Protein Expression in Human Embryos at the Pre-implantation Stage (R0165)

Roslin Cells Limited

- Platform Technologies Underpinning Human Embryonic Stem Cell Derivation (R0136)

Scottish Biomedical

- Derivation of a Human Embryonic Stem Cell Line for the Development of Drugs for Human Disease (R0182)

St Mary's Hospital, Manchester / Manchester Fertility Services / University of Manchester

- In vitro Development and Implantation of Normal Human Preimplantation Embryos and Comparison with Uni- or Poly- Pronucleate Pre-embryos (R0026)
- Derivation of Human Embryonic Stem Cell Lines from Embryos created from Clinically Unused Oocytes or Abnormally Fertilised Embryos (R0170/171)

University of Cambridge

- Derivation of Human Stem Cells from Human Surplus Embryos: The Development of hES Cultures, Characterisation of Factors Necessary for Maintaining Pluripotency and Specific Differentiation towards Transplantable Tissues (R0162)

University of Newcastle Upon Tyne, Centre for Stem Cell Biology & Developmental genetics, Institute of Human Genetics

- Derivation of Embryonic Stem Cell Lines from Interspecies Embryos Produced by Somatic Cell Nuclear Transfer (R0179)

University of Southampton

- Environmental Sensitivity of the Human Pre-Implantation Embryo (R0142)

University of York

- Biochemistry of Early Human Embryos (R0067)

Wellcome Trust Centre for Stem Cell Research, University College Cambridge

- Derivation of Pluripotent Human Embryo Cell Lines (R0132) (Previously R0132 - Institute of Stem Cell Research, Edinburgh)

Appendix 5

HFEA peer reviewers as at 31 March 2008:

Professor Lars Ahrlund-Richter

Director, Unit for Embryology and Genetics
Karolinska Institute, Sweden

Dr Siladitya Bhattacharya

Professor of Reproductive Medicine
University of Aberdeen

Dr Virginia Bolton

Consultant Embryologist
Assisted Conception Unit, Guy's and St Thomas's
Hospital London

Professor Nigel Brown

Dean, Faculty of Medicine and
Biomedical Sciences
St George's Hospital, University of London

Professor Keith Campbell

Professor of Animal Development
University of Nottingham

Professor Jose Cibelli

Professor of Biotechnology
Michigan State University, USA

Dr Mark Curry

Senior Lecturer
University of Lincoln

Ms Karin Dawson

Consultant Embryologist
Hammersmith Hospital, London

Professor Joy Delhanty

Emeritus Professor of Human Genetics
University College London

Dr Simon Fishel

Person Responsible/Managing Director
CARE Fertility Group

Dr Richard Fleming

Hon.Prof. Reproductive Medicine
Glasgow Royal Infirmary

Professor Stephen Franks

Professor of Reproductive Endocrinology
Hammersmith Hospital

Professor Alan Handyside

Chair of Developmental Biology
University of Leeds/London Bridge Fertility,
Gynaecology & Genetics Centre

Dr Joyce Harper

Senior Lecturer
University College London

Dr Geraldine Hartshorne

Scientific Director
Centre for Reproductive Medicine
University Hospitals Coventry
& Warwickshire NHS Trust

Professor Martin Johnson

Professor of Reproductive Science
University of Cambridge

Mr Charles Kingsland

Consultant Gynaecologist
Liverpool Women's Hospital

Dr Sue Kimber

Scientific Director North West Embryonic Stem
Cell Centre
University of Manchester

Professor Alan McNeilly

Programme Leader
MRC Human Reproductive Sciences Unit,
Edinburgh

Dr Tony Michael

Senior Lecturer Reproductive Science
St George's University of London

Professor Harry Moore

Professor, Centre for Stem Cell Biology
University of Sheffield

Professor Christine Mummery

ICIN Professor of Developmental Biology
Hubrecht Laboratory, The Netherlands

Dr Susan Pickering

Consultant Embryologist

Edinburgh Fertility and Reproductive
Endocrine Centre

Dr Helen Picton

Reader in Reproduction & Early Development
University of Leeds

Professor Ian Sargent

Professor of Reproductive Science
University of Oxford

Professor Austin Smith

Medical Research Council Professor & Director
Wellcome Trust Centre for Stem Cell Research,
University of Cambridge

Professor Miodrag Stojkovic

Deputy Director
Centro de Investigacion Principe Felipe, Spain

Professor Justin St John

Lecturer in Mitochondrial and
Reproductive Genetics
University of Birmingham

Professor Karl Swann

Chair in Reproductive Cell Biology
Cardiff University

Professor James Thompson

Professor, School of Medicine and
Public Health Anatomy

University of Wisconsin-Madison, USA

Professor Andre van Steirteghem
Emeritus Professor, Reproductive Medicine
and Genetics
Vrije University, Brussels, Belgium

Professor Robert Webb

Dean of the Faculty of Science
University of Nottingham

Professor Michael Whitaker

Professor of Physiology
University of Newcastle

Dr Maureen Wood

Research Embryologist
University of Aberdeen

Appendix 6

Members' interests - as at 31 March 2008 (or at end of term of office, if this was prior to 31 March 2008):

Name	Direct employment and consultancies	Fee-paid work other than HFEA	Shareholdings	Other public appointments and committee memberships	Other
Shirley Harrison (Chair until October 2007)	Director, Harrison Research & Consultancy Ltd	None	Small personal unit trust/savings	Chair, Human Tissue Authority Member, South Yorkshire Probation Board Magistrate	Member/Patients' Representative on various cancer research and education groups Member, Fellow Royal Society of Arts Member, Chartered Institute of Public Relations Member, Society of Authors Member, Magistrates' Association
Walter Merricks CBE (Interim Chair November 2007-March 2008)	Chief Ombudsman, Financial Ombudsman Service	None	A portfolio of shares managed by Heartwood Wealth Management Ltd	None	Chairman and Treasurer of Donor Conception Network
Hossam Abdalla	Director & PR at Lister Fertility Clinic Nominal Licensee at Agora Gynaecology and Fertility Centre	None	Various managed unit trusts	None	None
David Archard	Professor of Philosophy at Lancaster University	External examining	None	None	Royalties from academic publications

Name	Direct employment and consultancies	Fee-paid work other than HFEA	Shareholdings	Other public appointments and committee memberships	Other
Christopher Barratt	<p>Head of the Reproductive Biology and Genetics Research group at The University of Birmingham (until 30 August 2007)</p> <p>Professor of Reproductive Medicine at the University of Dundee (from 1 September 2007)</p> <p>Consultancy for Genosis - part of Scientific Advisory Board</p>	<p>Some work for solicitors, lectures, external examiner for PhD & MSc courses and occasional consultancy</p>	None	None	<p>Research licence at Birmingham Women's Hospital</p> <p>Research:</p> <p>The Birmingham Women's Hospital is licensed for research into chromatin and epigenetic changes associated with the development and generation of embryonic stem cells, and human gamete interaction and signalling</p>
Clare Brown	<p>Chief Executive, Infertility Network UK (INUK)</p>	None	None	None	<p>Patient representative on the British Fertility Society Management Committee</p> <p>Member of the European Society of Human Reproduction and Embryology</p> <p>Member of the Labour Party</p> <p>Chair of the National Infertility Awareness Campaign</p> <p>Chair of the Organising Committee of National Infertility Day</p> <p>Member of the European Infertility Alliance</p> <p>Founder Member of Fertility Europe</p>

Name	Direct employment and consultancies	Fee-paid work other than HFEA	Shareholdings	Other public appointments and committee memberships	Other
Anna Carragher	None	None	Equity Unit Trust	Trustee, Grand Opera House, Belfast Chair, Grand Opera House Belfast Trust	None
Sally Cheshire	Self-employed management consultant	NHS Northwest (Strategic Health Authority) - non-executive Director & Chair of Audit Committee	None	Chair - Samaritans Branch in Manchester Area	None
Rebekah Dundas	Programme Manager, Big Lottery Fund	None	None (small personal savings in tracker ISA)	None	Member, INUK Member, Donor Conception Network
Ruth Fasht OBE	Management Consultancy on Childcare; social work; fostering and adoption services and related issues	None	None	None	Member, Norwood Council Member, Institute of Group Analysis Member, Council, Sensory Processing Foundation
Neva Haites OBE	Vice Principal and Head of College of Life Science and Medicine Member of the Board NHS Grampian	External Examiner for the University of Malaya Medicines and Healthcare products Regulatory Agency (MHRA) - Expert Advisory Groups	Jointly with husband - Weatherford Managed funds including a selection of shares selected by the Management Consultants	Member MRC/ Human Stem Cell Network Panel Chair of the Biomedical and Therapeutics Research Committee of Chief Scientists Office Scotland	Member, British Society of Human Genetics European Society of Human Genetics Royal College of Physicians (Fellow) of Edinburgh and London Royal Society of Pathology (Fellow) Fellow Academy of Medical Science

Name	Direct employment and consultancy	Fee-paid work other than HFEA	Shareholdings	Other public appointments and committee memberships	Other
Lord (Richard) Harries of Pentregarth	None	Occasional journalism, lectures and books	None	Member of Nuffield Council on Bioethics	None
Jennifer Hunt	Senior Infertility Counsellor, IVF Hammersmith	None	None	None	Membership of: British Infertility Counselling Association British Fertility Society British Association for Counselling and Psychotherapy National Accreditation Board for Infertility Counselling Project Group on Assisted Reproduction UK Donorlink Advisory Group
Emily Jackson	Professor of Law at the London School of Economics	External examining Occasional honoraria for lectures and for acting in an advisory capacity	None	Member of: BMA Medical Ethics Committee Royal College of Physicians Committee on Ethical Issues in Medicine Royal College of Pathologists Ethics Committee	Author royalties from academic publishers
Maybeth Jamieson	Consultant Embryologist, Assisted Conception Service, Glasgow Royal Infirmary	None	Scottish Power plc	None	Member of the Association of Clinical Embryologists Embryology Assessor for the Association of Clinical Scientists Member of the European Society for Human Reproduction and Embryology Member of the British Fertility Society

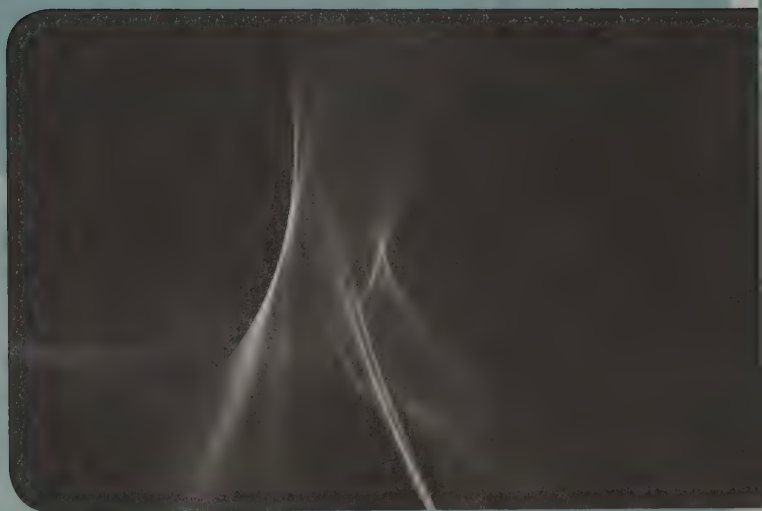


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Human Fertilisation and
Embryology Authority

Name	Direct employment and consultancies	Fee-paid work other than HFEA	Shareholdings	Other public appointments and committee memberships	Other
William Ledger	Professor of Obstetrics and Gynaecology, University of Sheffield Honorary Consultant at the Sheffield Teaching Hospitals Trust Member Advisory Board - Ferring Ltd	Honoraria for various academic presentations at scientific meetings	Director of Lifestyle Choices Ltd	None	Chair - Examination Committee, Royal College of Obstetricians and Gynaecologists Research Funding from Akzonobel, Ferring and Pfizer
Sharmila Nebhrajani	Chief Operating Officer and Finance Director, BBC Future Media & Technology	Board Member, Charity Commission Member of the Olympic Lottery Distributor	Small personal shareholdings in selected PLCs	None	Audit Committee Member, Royal Shakespeare Company
Roger Neuberg	Consultant Obstetrician and Gynaecologist, Leicester Royal Infirmary	None	Small number of shares following demutualisation of two insurance companies	None	Chairman and Trustee of Advanced Life Support Training in Obstetrics for Healthcare Professionals (ALSO UK) Member of British Fertility Society Member of the European Society of Human Reproduction and Embryology Member of MRC Joint Stem Cell User and Clinical Liaison Committee

Name	Direct employment and consultancies	Fee-paid work other than HFEA	Shareholdings	Other public appointments and committee memberships	Other
Susan Price	Consultant in Clinical Genetics, Northamptonshire	Occasional work as an expert in legal cases requiring specialist genetic reports.	None	None	<p>Member, British Society of Human Genetics</p> <p>European Society of Human Genetics</p> <p>Royal College of Physicians (Fellow)</p> <p>Skeletal Dysplasia Group</p> <p>Leicester, Northamptonshire and Rutland Research Ethics Committee II</p> <p>Genethics Club (a national forum to discuss ethical issues in genetics)</p>



04

Remuneration Report



Remuneration Report

The HFEA implements its remuneration recommendations based on the Civil Service Pay Guidelines issued annually by the Treasury. As such our reward systems are aligned to central government recommendations that they should:

- Be tailored to reflect organisational needs and are sufficiently flexible to enable them to adjust to changing business circumstances
- Improve the operation of the delegated pay arrangements by reducing divergence for staff with similar skills, doing similar work from the same relevant labour market where this is not justified by business needs
- Support the public service ethos and values, are transparent, and meet the commitment to equal pay
- Recognise and reward results and performance – pay should reflect output, results and performance with the best performers (both individual and/or teams) and those who contribute the most receiving the highest reward.

Pay remits fell into one of two bands in 2007, depending on the amount being sought. For Departments that are considered to be higher paying, relative to others in the same relevant labour market, the expectation was an increase for staff in post of between 2.0% and 3.5%. For Departments who could demonstrate that they were lower paying, relative to those in the same relevant labour market, the expectation was an increase for staff in post of between 3.5% and 4.5%. HFEA fell into the former category.

Any reward agreements must also be within the HFEA budget set through the Arm's Length Body (ALB) team at the Department of Health.

Reward Systems and Approval Mechanisms

Pay levels are reviewed on an annual basis through the Resources (formerly Organisation and Finance) Committee which has specific responsibility to 'monitor overall levels of remuneration and specifically approve the remuneration of the Interim Chief Executive and Directors'.

The Pay Award comprises two elements – cost of living increase and an element for Performance Related Pay (PRP). Performance related pay is currently determined through the Performance Development Planning (PDP) process as outlined in HFEA's PDP and Performance Management Guidelines (revised April 2006 and 2008).

Duration of Contracts, Notice Periods and Termination Payments

Members of staff in Bands 1 (Assistant grade) and 2 (Officer grade) are required to give the Authority 6 weeks notice of termination of contract, and the Authority is required to provide them with 6 weeks notice of termination of contract. Members of staff in Band 3 (Manager grade) and above are required to give the Authority 3 months notice, and the Authority is required to provide them with 3 months notice of termination of contract. Termination payments are made only in the appropriate circumstances and may arise when staff are not required to work their period of notice, with the exception of cases where gross misconduct has arisen in which case no termination payment is made.

Chair and Non Executive Members

The remuneration levels of the Chair and Non-Executive Authority Members are set nationally. Revisions to these pay levels are made in accordance with the agreement on the Pay Framework for ALB Chairs and Non-Executive Directors, announced in March 2006. The HFEA implements the revisions when instructed.

Chief Executive and Directors

The remuneration level of the Chief Executive is currently recommended by the Chair, subject to approval through the Resources Committee, and agreed with the sponsor branch at the Department of Health.

Remuneration levels for Directors must be approved through the Resources Committee.

All Staff

In line with the PDP process, all staff are assessed on their performance and given a 'box marking' which is then translated into performance related pay. The same criteria and percentages are applied to all staff, including Directors. To ensure consistency and fairness across the organisation there is a moderation process.

The recommendations for revised salary bands and remuneration for each post was reviewed by the Senior Management Team and agreed through the Resources Committee.

New posts

All new posts or posts with changed responsibilities are subject to a formal job evaluation process (Paypoints II) before recommendations for changes to pay.

Appointments

All appointments are made in accordance with the HFEA's Recruitment and Selection Policy (revised January 2007). The aim is to ensure that all appointments of HFEA staff are made on the basis of merit and in accordance with equal opportunities.

Retirement

Staff may access their Civil Service pension from the age of 60. However, the HFEA recognises that some staff may wish to work beyond this age. In line with the Employment Equality (Age) Regulations 2006, the HFEA introduced a new Retirement Policy in October 2006 which introduces a default retirement age of 65. Staff have the opportunity to request working beyond the age of 65 and to have this request seriously considered.

Early termination, other than for misconduct, would result in the individual receiving compensation as set out in the Civil Service Compensation Scheme.

Salary and pension entitlements

The following sections provide details of the remuneration and pension interests of the Senior Management Team.

Chief Executive: Ms Angela McNab

On 1 October 2007 Ms McNab went on secondment to the Department of Health as Director of Public Health, Performance and Delivery. In the period 1 April 2007 to 30 September 2007, the salary and pension entitlements of Ms McNab from the HFEA were as follows:

Salary	Real Increase in Pension at age 60	Real increase in lump sum	Total Accrued Pension at age 60 at 31/3/08	Related Lump Sum at 31/3/08	CETV at 1/4/07	CETV at 31/3/08	Real increase in CETV as funded by HFEA
Band £'000	Band £'000	Band £'000	Band £'000	Band £'000	nearest £'000	nearest £'000	nearest £'000
60-65 (2006/07 115-120)	0-2.5 (2006/07 0-2.5)	2.5-5 (2006/07 2.5-5)	15-20 (2006/07 15-20)	55-60 (2006/07 50-55)	298	371	25

Taxable benefits in kind totalling £191 (2006/07 £418) were paid to Ms McNab during the year in respect of mobile telephone rental costs. The HFEA meets the resulting tax liability under a PAYE settlement agreement.

Interim Chief Executive: Mr Alan Doran CB

From 1 October 2007 Mr Alan Doran CB was appointed as interim Chief Executive to the Authority. In the period 1 October 2007 to 31 March 2008, the salary and pension entitlements of Mr Doran were as follows:

Salary	Real Increase in Pension at age 60	Real increase in lump sum	Total Accrued Pension at age 60 at 31/3/08	Related Lump Sum at 31/3/08	CETV at 1/4/07	CETV at 31/3/08	Real increase in CETV as funded by HFEA
Band £'000	Band £'000	Band £'000	Band £'000	Band £'000	nearest £'000	nearest £'000	nearest £'000
75-80	2.5-5	0-2.5	80-85	0-5	1,510	1,734	95

Mr Doran's salary and associated costs were paid by the Department of Health, and a proportion of these were reimbursed by the HFEA. No taxable benefits in kind were paid by the HFEA to Mr Doran.



Other Senior Managers

The Government Financial Reporting Manual requires the HFEA to provide information on the salary and pension rights of the named individuals who are the "most senior managers" of the HFEA, subject to the individuals concerned consenting to disclosure.

The salary and pension entitlements of the Senior Managers in the HFEA during the period were as follows:

Name of Senior Manager	Salary	Real Increase in Pension at age 60	Real increase in lump sum	Total Accrued Pension at age 60 at 31/3/08	Related Lump Sum at 31/3/08	CETV at 1/4/07	CETV at 31/3/08	Real increase in CETV as funded by HFEA
	Band £'000	Band £'000	Band £'000	Band £'000	Band £'000	nearest £'000	nearest £'000	nearest £'000
Trish Davies – Deputy Chief Executive	90-95 (2006/07 90-95)	0-2.5 (2006/07 0-2.5)	0-2.5 (2006/07 0-2.5)	15-20 (2006/07 10-15)*	0-5 (2006/07 0-5)	287*	357	31
**Richard Cullen – Director of Information (from 24 September 2007)	65-70							
***Maggie King – Director of Strategic Change (from 21 January 2008)	15-20	0-2.5	0-2.5	30-35	95-100	621	651	14
David Tellis – Director of Information (to 21 September 2007)	35-40 (2006/07 75-80)	0-2.5 (2006/07 0-2.5)	0-2.5 (2006/07 0-2.5)	5-10 (2006/07 5-10)	0-5 (2006/07 0-5)	63	69	7
Tim Whitaker – Director of Policy and Communication	80-85 (2006/07 75-80)	0-2.5 (2006/07 0-2.5)	2.5-5 (2006/07 0-2.5)	25-30 (2006/07 25-30)	80-85 (2006/07 75-80)	443	528	19
Sally Townsend – Director of Resources	70-75 (2006/07 60-65)	0-2.5 (2006/07 0-2.5)	0-2.5 (2006/07 0-2.5)	0-5 (2006/07 0-5)	0-5 (2006/07 0-5)	13	34	12

* The accrued pension for Trish Davies as at 31 March 2007 was stated in the Annual Report and Accounts for 2006/07 in the band of £20k-£25k, and the CETV as at 31 March 2007 was stated at £469k. The basis of calculations for these figures was subsequently found to be incorrect. The correct figures are as stated above.

** Mr Richard Cullen's salary was non-pensionable during the period.

*** Ms Maggie King was on secondment from the Department of Health during the period 21 January – 31 March 2008. Ms King's salary and associated costs were paid by the Department of Health, and reimbursed by the HFEA.



Salary

'Salary' includes gross salary, performance pay or bonuses, and any other allowance to the extent that it is subject to UK taxation. This report is based on payments made by the HFEA and thus recorded in these accounts.

Benefits in Kind

The monetary value of benefits in kind covers any benefits provided by the employer and treated by the Inland Revenue as a taxable emolument.

Civil Service Pensions

As per 2001 Statutory Instrument No. 1587, HFEA staff were conditionally admitted to the Principal Civil Service Pension Scheme (PCSPS) as from 1st April 2000, transferring from the HFEA by-analogy Scheme.

The PCSPS is an unfunded multi-employer defined benefit scheme but the HFEA is unable to identify its share of the underlying assets and liabilities. A full actuarial valuation was carried out as at 31 March 2007 by the Scheme Actuary, Hewitt Bacon Woodrow. Details can be found in the resource accounts of the Cabinet Office: Civil Superannuation (www.civilservice-pensions.gov.uk).

Pension benefits are provided through the Civil Service pension arrangements. From 30 July 2007, staff may be in one of four defined benefit schemes; either a "final salary" scheme (Classic, Premium, or Classic Plus) or a "whole career" scheme (Nuvos). The statutory arrangements are unfunded with the cost of benefits met by monies voted by Parliament each year. Pensions payable under Classic, Premium, Classic Plus and Nuvos are increased annually in line with changes in the Retail Prices Index (RPI.) New entrants joining from October 2002 may opt for either the appropriate defined benefit arrangement or a good quality "money purchase" stakeholder pension with a significant employer contribution (Partnership Pension Account.)

Employee contributions are set at the rate of 1.5% of pensionable earnings for Classic and 3.5% for Premium, Classic Plus and Nuvos. Benefits in Classic accrue at the rate of 1/80th of final pensionable earnings for each year of service. In addition, a lump sum equivalent to three years' pension is payable on retirement. For Premium, benefits accrue at the rate of 1/60th of final pensionable earnings for each year of service. Unlike Classic, there is no automatic lump sum (but members may give up (commute) some of their pension to provide a lump sum). Classic Plus is essentially a hybrid with benefits in respect of service before 1 October 2002 calculated broadly as per Classic and benefits for service from October 2002 calculated as in Premium. In Nuvos a member builds up pension based on his or her pensionable earnings during their period of scheme membership. At the end of the scheme year (31 March) the member's earned pension account is credited with 2.3% of their pensionable earnings in that scheme year and the accrued pension is uprated in line with RPI. In all cases members may opt to give up (commute) pension for lump sum up to the limits set by the Finance Act 2004.

The Partnership Pension Account is a stakeholder pension arrangement. The employer makes a basic contribution of between 3% and 12.5% (depending on the age of the member) into a stakeholder pension product chosen by the employee from a panel of three providers. The employee does not have to contribute but where they do make contributions, the employer will match these up to a limit of 3% of pensionable salary (in addition to the employer's basic contribution). Employers also contribute a further 0.8% of pensionable salary to cover the cost of centrally-provided risk benefit cover (death in service and ill health retirement.)

The accrued pension quoted is the pension the member is entitled to receive when they reach pension age, or immediately on ceasing to be an active member of the scheme if they are already at or over pension age. Pension age is 60 for members of Classic, Premium, and Classic Plus and 65 for members of Nuvos.

For 2007/08, employers' contributions of £629,013 were payable to the PCSPS (2006/07 £633,542) at one of four rates in the range 17.1% to 25.5% (2006/07 17.1% to 25.5%) of pensionable pay, based on salary bands. The scheme's actuary reviews employer contributions every four years following a full scheme valuation. From 2008/09, the salary bands will be revised, but the rates will remain the same. (The rates will be changing with effect from April 2009.) The contribution rates are set to meet the cost of benefits accruing during 2007/08 to be paid when the member retires, and not the benefits paid during this period to existing pensioners.

For 2007/08, Partnership Pension Account employer's contributions of £2,438 were paid (2006/07 £5,247) to one or more companies chosen by employees from the panel of three appointed stakeholder pension providers. No contributions were due or prepaid to the partnership pension providers at the balance sheet date (2006/07 £nil).

Further details about the Civil Service pension arrangements can be found at the website www.civilservice-pensions.gov.uk.

Cash Equivalent Transfer Values

The tables on pages 50 and 51 show the members' Cash Equivalent Transfer Value (CETV) accrued at the beginning and the end of the reporting period as provided by the Civil Service Pension Scheme

A CETV is the actuarially assessed capitalised value of the pension scheme benefits accrued by a member at a particular point in time. The benefits valued are the member's accrued benefits and any contingent spouse's pension payable from the scheme. A CETV is a payment made by a pension scheme or arrangement to secure pension benefits in another pension scheme or arrangement when the member leaves a scheme and chooses to transfer the benefits accrued in their former scheme.

The pension figures shown relate to the benefits that the individual has accrued as a consequence of their total membership of the pension scheme, not just their service in a senior capacity to which disclosure applies. The figures include the value of any pension benefit in another scheme or arrangement which the individual has transferred to the Civil Service pension arrangements. They also include any additional pension benefit accrued to the member as a result of their purchasing pension benefits at their own cost.

CETVs are calculated within the guidelines and framework prescribed by the Institute and Faculty of Actuaries and do not take account of any actual or potential reduction to benefits resulting from Lifetime Allowance Tax which may be due when pension benefits are drawn.

Due to certain factors being incorrect in last year's CETV calculator there may be a slight difference between the final period CETV for 2006/07 and the start of the period CETV for 2007/08.

Real Increase in Cash Equivalent Transfer Values

This reflects the increase in CETV effectively funded by the employer. It does not include the increase in accrued pension due to inflation, contributions paid by the employee (including the value of any benefits transferred from another pension scheme or arrangement) and uses common market valuation factors for the start and end of the period.

Register of Interests

The HFEA maintains a Register of Interests which details company directorships and other significant interests declared by senior management. Persons wishing to view the Register should apply in writing to the Director of Resources and Corporate Development at the HFEA.



Remuneration of Authority Members

Membership of the Human Fertilisation and Embryology Authority during the year ended 31 March 2008 was as follows:

Ms Shirley Harrison

(Chair, resigned 31 October 2007)

Mr Walter Merricks CBE

(Interim Deputy Chair from 5 September to 31 October 2007; Acting Chair from 1 November 2007 to 31 March 2008)

Ms Sharmila Nebhrajani

(Deputy Chair to 25 July 2007, then from 9 January 2008 onwards)

Mr Hossam Abdalla

(Re-appointed 30 September 2007)

Professor David Archard

Professor Christopher Barratt (Re-appointed 7 November 2007)

Ms Clare Brown

Ms Anna Carragher

Ms Sally Cheshire

(Chair of the Audit Committee)

Ms Rebekah Dundas

Ms Ruth Fasht OBE

Professor Neva Haites OBE

Lord (Richard) Harries of Pentregarth

Ms Jennifer Hunt

Ms Emily Jackson

Dr Maybeth Jamieson

Professor William Ledger

Mr Roger Neuberg

Dr Sue Price

In the year ended 31 March 2008 the HFEA's share of the salary of Shirley Harrison as Chair from 1 April 2007 to 31 October 2007 was in the band £15k - £20k (2006/07 £7.5k-£10k). No pension contributions were paid.

In addition to the foregoing, the HFEA's share of Shirley Harrison's benefits in kind in respect of reimbursement of travel and subsistence costs arising from her home base being out of London, amounted to £5,806 (2006/07 £1,843). The HFEA meets its share of the resulting tax liability under a PAYE settlement agreement.

In the period 1 November 2007 – 31 March 2008 the salary of Walter Merricks CBE as Chair was in the band £5k to £10k. No pension contributions were paid.

Other Members' Remuneration

The Deputy Chairman received a fee of £200 per day. The Chair of the Audit Committee received a fee of £263 per day. Members received a fee of £183 per day. No pension contributions were paid on behalf of any Board Member. Remuneration payable to individual members for attendance at meetings and inspections during the period was in the following bands:

£0 - £5,000

Professor David Archard

Professor Christopher Barratt

Ms Rebekah Dundas

Professor Neva Haites OBE

Lord (Richard) Harries of Pentregarth

Professor William Ledger

Mr Walter Merricks CBE

Ms Sharmila Nebhrajani

Dr Sue Price

£5,001 - £10,000

Mr Hossam Abdalla

Ms Clare Brown

Ms Anna Carragher

Ms Sally Cheshire (Chair of the Audit Committee)

Ms Ruth Fasht OBE

Ms Jennifer Hunt

Ms Emily Jackson

Dr Maybeth Jamieson

Mr Roger Neuberg

Audit

Certain of the disclosures in the Remuneration Report are subject to audit. These include salaries and allowances, bonuses, expense allowances, compensation for loss of office and non-cash benefits for each senior manager together with advisory and non-executive Board members who served during the year.

Register of Interests

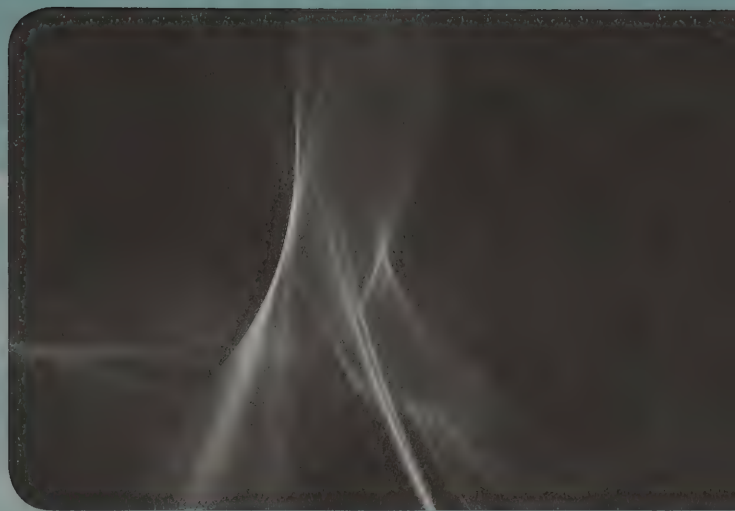
Details of company directorships and other significant interests declared by Authority Members can be found in Appendix 6 or at the website www.hfea.gov.uk.



Mr Alan Doran CB

Interim Chief Executive

10 June 2008



05

Statement of the
Authority's and
Interim Chief
Executive's
Responsibilities





Statement of the Authority's and Interim Chief Executive's Responsibilities

Authority Members' Responsibilities

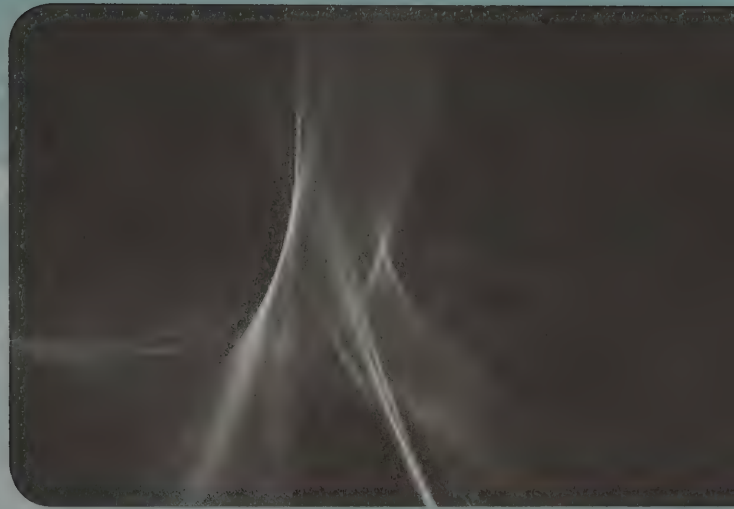
Under section 6(1) of the Human Fertilisation and Embryology Act 1990, the Human Fertilisation and Embryology Authority is required to prepare a statement of accounts for each financial year in the form and on the basis determined by the Secretary of State, with the Treasury. The accounts are prepared on the accruals basis, and must show a true and fair view of the Authority's state of affairs at the year-end and of its income and expenditure, total recognised gains and losses, and cash flow for the financial year.

In preparing the accounts the Authority is required to comply with the requirements of the Government Financial Reporting Manual and in particular to:

- Observe the Accounts Directions issued by the Secretary of State, including the relevant accounting and disclosure requirements, and apply suitable accounting policies on a consistent basis
- Make judgements and estimates on a reasonable basis
- State whether applicable accounting standards as set out in the Government Financial Reporting Manual have been followed, and disclose and explain any material departures in the financial statements
- Prepare the financial statements on the going concern basis unless it is inappropriate to presume that the Authority will continue in operation.

Accounting Officer's Responsibilities

The Accounting Officer of the Department of Health has designated the Interim Chief Executive of the Human Fertilisation and Embryology Authority as the Accounting Officer for the Authority. His relevant responsibilities as Accounting Officer, including his responsibility for the propriety and regularity of the public finances for which he is answerable, for the keeping of proper records, and for safeguarding the Authority's assets are set out in the Non Departmental Public Bodies' Accounting Officer Memorandum.



06 Statement on Internal Control





Statement on Internal Control

Scope of responsibility

As Accounting Officer, I have responsibility for maintaining a sound system of internal control that supports the achievement of the HFEA's policies, aims and objectives, as set out in the Human Fertilisation and Embryology Act 1990, the Authority's Business Plan, and by Ministers within the Department of Health (DH), whilst safeguarding the public funds and departmental assets for which I am personally responsible, in accordance with the responsibilities assigned to me in Department of Health correspondence.

The Management Statement, agreed between the Department of Health and the HFEA, sets out the accountability framework within which the Authority's work will be monitored. This requires:-

- Prior approval by the Department of the HFEA's Annual Business Plan, including an assessment of risks to the organisation;
- Submission to the Department of quarterly monitoring information on progress in implementing the Business Plan;
- An annual accountability meeting between DH Ministers and the Chair and Interim Chief Executive of the HFEA.

Department of Health representatives regularly attend Authority meetings, and meetings of the Audit Committee. The rapid pace of change within the HFEA has continued throughout 2007/08, and close liaison has been maintained with the Department throughout. In addition to the formal accountability framework, there have been regular meetings with the Department of Health sponsor team and Arm's Length Bodies Business Support Unit.

The purpose of the system of internal control

The system of internal control is designed to manage risk to a reasonable level rather than to eliminate all risk of failure to achieve policies, statutory functions, aims and objectives; it can therefore only provide reasonable and not absolute assurance of effectiveness.

The system of internal control is based on an ongoing process designed to identify and prioritise the risks to the achievement of the HFEA's policies, statutory functions, aims and objectives. It also evaluates the likelihood of those risks being realised, the impact should they be realised, and the controls in place to manage them efficiently, effectively and economically. The system of internal control has been in place in the HFEA for the year ended 31 March 2008 and up to the date of approval of the annual report and accounts, and accords with Treasury guidance.

Capacity to handle risk

The HFEA operates in a high risk area with a significant public profile, which means that all decisions can be heavily scrutinised. Therefore it is critically important that risks are identified and managed appropriately. The HFEA's risk management process aims to help Members and staff to consider risk, its probability and impact, and the controls in place for management and mitigation purposes, in a consistent manner. The process also recognises that risk exposure varies with new activities, or changes to existing activities, and therefore regular reviews are conducted.

The Audit Committee records and reviews strategic risks associated with achievement of key Business Plan objectives, using a framework based on the Treasury model. High level risks for the coming year are also recorded in the HFEA's annual business plan.



It is recognised that effective risk management must be resourced, and this is reflected in the organisation and staffing levels. During the past year, the HFEA's high level risk register was reviewed regularly by both the Senior Management Team (SMT) and a staff Risk Management Group. In April 2008, we replaced these meetings with a Corporate Management Group consisting of key managers including the SMT, and this retains the function of reviewing high level risks on a monthly basis, and any other risk issues as and when they arise.

The Head of Business Planning has specific responsibility for supporting risk management across the organisation and inducting new staff in risk management processes. All operational managers are actively involved in risk management. Key service Heads were members of the Risk Management Group and are also represented on the new Corporate Management Group.

A review of lessons learned from the HFEA's high level risk handling is presented to the Audit Committee annually, and relevant learning points from this are incorporated into the HFEA's Manager's Guide to Risk Management.

The risk and control framework

The HFEA attitude to risk is to adopt a well-balanced approach. Risk is defined as anything that may jeopardise the Authority's ability to perform its statutory functions, and anything that may lead to an inability to achieve Business Plan objectives. This could also include the failure to identify and take advantage of new opportunities.

The main focus for consideration of risk is the High Level Risk Register, which identifies the probability and impact of each risk and the mitigating controls that are in place. As a regulator, the HFEA's intrinsic risk appetite is low. The risk management process therefore also includes consideration of the tolerability of each residual

risk, with a requirement to include an action plan (or an impact handling plan) where residual risks are deemed too high. The Risk Register has been regularly monitored during the year by the executive, a function now performed by the Corporate Management Group. A review of the effectiveness of the 2007/08 controls within the High Level Risk Register was presented to the Audit Committee in May 2008 (this is the review of lessons learned, referred to above).

The high level risk register is underpinned by a system of individual departmental operational risk logs. This operational risk system enables risks, if relevant, to be escalated to the High Level Risk Register via Directors or the Head of Business Planning. In this way, serious issues are referred to the Corporate Management Group for detailed consideration.

The assessment of risks is integrated into the business planning process, and the Business Plan incorporates current risks and the actions already taken to manage key risks. The system of internal control includes an identification of key risks associated with delivery of operational objectives within each Directorate, and within individual projects, and the controls to mitigate them.

In accordance with our responsibilities under section 33 of the HFE Act 1990, the HFEA has in place various robust and specific arrangements to ensure information security, including a Security Policy that applies to all staff. Other arrangements include secure and confidential storage of and limited access to Register information, the prevention of any unauthorised use of removable media such as USB memory sticks and data CDs with HFEA laptops and PCs, and a fixed asset register to track the location of items of IT equipment. The HFEA has stringent encryption standards, and has a standard data wiping process for all obsolete and retired computer equipment. The HFEA also operates a clear desk policy, and has on-site shredders and confidential disposal arrangements in place.



Changing Environment

In 2008/09, a number of pieces of recent and new legislation will profoundly affect the way the HFEA will operate in future. The Human Fertilisation and Embryology Bill will affect what and how the HFEA regulates, and the range of information the HFEA collects and releases to other people. A Regulators' Compliance Code has been introduced, which the HFEA must comply with. The Regulatory Enforcement and Sanctions (RES) Bill, covers the operation of a large number of Government regulators, including the HFEA. The HFEA has already commenced assessment of its own compliance with this, and work will continue throughout 2008/09.

As Interim Chief Executive since October 2007, I have initiated a comprehensive review of how the HFEA works as an organisation, to prepare for all of these changes. Through this review, called Programme 2010, the HFEA will ensure that future ways of working will be as efficient and effective as possible, and that the HFEA remains fit for purpose as a world leading regulator in healthcare. Clinics and other stakeholders will be involved in this work as it progresses.

The overarching risk to the organisation will continue to be delivering an increasingly expanding agenda, with limited resource levels, against a back-drop of legislative change, constant public interest and media scrutiny.

Key risks to the organisation and the mitigating actions in place to reduce the overall risk level are included on pages 19 and 20 of this document.

Review of effectiveness

As Accounting Officer, I have responsibility for reviewing the effectiveness of the system of internal control. My review of the effectiveness of the system of internal control is informed by the work of the internal auditors and the executive managers within the HFEA who have responsibility for the development and maintenance of the internal control framework, and comments made

by the external auditors in their management letter and other reports. I have been advised on the implications of the result of my review of the effectiveness of the system of internal control by the Authority, the Audit Committee, the Senior Management Team and the Corporate Management Group, and a plan to address weaknesses and ensure continuous improvement of the system is in place.

The HFEA's approach to risk includes an organisation-wide process for reviewing risk and monitoring the implementation and effectiveness of management controls. This takes place at departmental level, and through the SMT, the Corporate Management Group, Standing Committees, the Authority itself, and internal audit.

The Authority reviews the effectiveness of risk management twice during the year, and receives a full report from the Audit Committee at the year end.

The Audit Committee is the main source of assurance to the Authority on the effectiveness of risk management, and receives a report on risk at each meeting. The risk management format was expanded to include consideration of the tolerability of residual risks and the addition of any necessary action plans during 2007.

Directors and Departmental Heads are actively involved in ensuring operational and high level strategic risks are identified and managed. Training on best practice risk management techniques and processes is being planned for staff and Members in the 2008/09 business year.

In the 2007/08 year, the HFEA had in place a Risk Management Group (RMG), to monitor emerging risks and the implementation of controls over known risks, and to review and where necessary improve the HFEA's risk management systems. In 2008/09, this function has been explicitly taken over by the recently formed Corporate Management Group. Both groups have been facilitated and supported by the Head of Business Planning.

Programme and Project level controls are also in place. Project and Programme Managers consider the risks associated with delivery of their objectives within each project. All new pieces of work proposed must have a supporting project initiation document (PID), which contains an analysis of the risks of doing and not doing the work.

It is recognised that all staff must be involved in, and have some understanding of, risk management. The Head of Business Planning and other operational managers within the HFEA, particularly those serving on the Corporate Management Group, are a key focus in developing this awareness. The planned training will further enhance this.

The Internal Audit Team has reviewed the management of key areas of work during the year. They have reported to the Audit Committee that in respect of the arrangements made by the Authority and examined by them for the year to 31 March 2008 for risk management, control and governance and economy, efficiency and effectiveness, they found no fundamental weaknesses or deficiencies and were of the opinion that the Authority could rely on the arrangements in all material respects.

The corporate risk process now in place serves to highlight the inter-relationships between key risks, and the importance of a coordinated approach to managing them.

It is also recognised that the management of risk is an integral part of the wider business

planning process, and risk management will be strengthened further during delivery of the

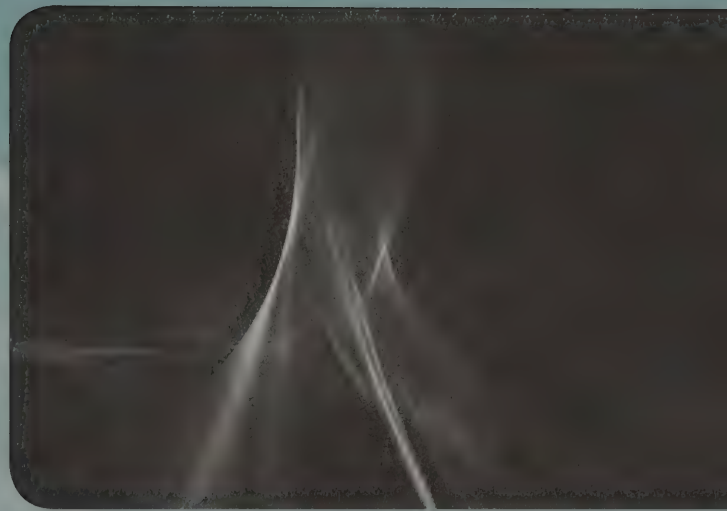
2008/09 Business Plan and the Programme 2010 organisational development work.



Mr Alan Doran CB

Interim Chief Executive

10 June 2008



07

The Certificate
and Report of the
Comptroller and
Auditor General
to the Houses of
Parliament





The Certificate and Report of the Comptroller and Auditor General to the Houses of Parliament

I certify that I have audited the financial statements of the Human Fertilisation and Embryology Authority (the Authority) for the year ended 31 March 2008 under the Human Fertilisation and Embryology Act 1990. These comprise the Income and Expenditure Account, the Balance Sheet, the Cashflow Statement and Statement of Total Recognised Gains and Losses and the related notes. These financial statements have been prepared under the accounting policies set out within them. I have also audited the information in the Remuneration Report that is described in that report as having been audited.

Respective responsibilities of the Authority, Interim Chief Executive and Auditor

The Authority and Interim Chief Executive are responsible for preparing the Annual Report, the Remuneration Report and the financial statements in accordance with the Human Fertilisation and Embryology Act 1990 and directions made thereunder by the Secretary of State with the approval of Treasury and for ensuring the regularity of financial transactions. These responsibilities are set out in the Statement of the Authority's and Interim Chief Executive's Responsibilities.

My responsibility is to audit the financial statements and the part of the remuneration report to be audited in accordance with relevant legal and regulatory requirements, and with International Standards on Auditing (UK and Ireland).

I report to you my opinion as to whether the financial statements give a true and fair view and whether the financial statements and the part of the Remuneration Report to be audited have been properly prepared in accordance with the Human Fertilisation and Embryology Act 1990 and directions made thereunder by the Secretary of State with the approval of Treasury. I report to you whether, in my opinion, the Chair's and Interim Chief Executive's Foreword, a Management Commentary, Appendices and the unaudited part of the Remuneration Report, included in the Annual Report is consistent with the financial statements. I also report whether in all material respects the expenditure and income have been applied to the purposes intended by Parliament and the financial transactions conform to the authorities which govern them.

In addition, I report to you if the Authority has not kept proper accounting records, if I have not received all the information and explanations I require for my audit, or if information specified by HM Treasury regarding remuneration and other transactions is not disclosed.

I review whether the Statement on Internal Control reflects the Authority's compliance with HM Treasury's guidance, and I report if it does not. I am not required to consider whether this statement covers all risks and controls, or form an opinion on the effectiveness of the Authority's corporate governance procedures or its risk and control procedures.

I read the other information contained in the Annual Report and consider whether it is consistent with the audited financial statements. This other information comprises the Chair's and



Interim Chief Executive's Foreword, a Management Commentary, Appendices and a Remuneration Report. I consider the implications for my report if I become aware of any apparent misstatements or material inconsistencies with the financial statements. My responsibilities do not extend to any other information.

Basis of audit opinions

I conducted my audit in accordance with International Standards on Auditing (UK and Ireland) issued by the Auditing Practices Board. My audit includes examination, on a test basis, of evidence relevant to the amounts, disclosures and regularity of financial transactions included in the financial statements and the part of the Remuneration Report to be audited. It also includes an assessment of the significant estimates and judgments made by the Authority and Accounting Officer in the preparation of the financial statements, and of whether the accounting policies are most appropriate to the Authority's circumstances, consistently applied and adequately disclosed.

I planned and performed my audit so as to obtain all the information and explanations which I considered necessary in order to provide me with sufficient evidence to give reasonable assurance that the financial statements and the part of the Remuneration Report to be audited are free from material misstatement, whether caused by fraud or error, and that in all material respects the expenditure and income have been applied to the purposes intended by Parliament and the financial transactions conform to the authorities which govern them. In forming my opinion I also evaluated the overall adequacy of the presentation of information in the financial statements and the part of the Remuneration Report to be audited.

Opinions

In my opinion:

the financial statements give a true and fair view, in accordance with the Human Fertilisation and Embryology Act 1990 and directions made thereunder by the Secretary of State with the approval of Treasury, of the state of Human Fertilisation and Embryology Authority's affairs as at 31 March 2008 and of its deficit for the year then ended;

the financial statements and the part of the Remuneration Report to be audited have been properly prepared in accordance with the Human Fertilisation and Embryology Act 1990 and directions made thereunder by the Secretary of State with the approval of Treasury; and information, which comprises the Chair's and Interim Chief Executive's Foreword, a Management Commentary, Appendices and the unaudited part of the Remuneration Report, included in the Annual Report is consistent with the financial statements.

Audit Opinion on Regularity

In my opinion, in all material respects the expenditure and income have been applied to the purposes intended by Parliament and the financial transactions conform to the authorities which govern them.

Report

I have no observations to make on these financial statements.

T J Burr

Comptroller and Auditor General

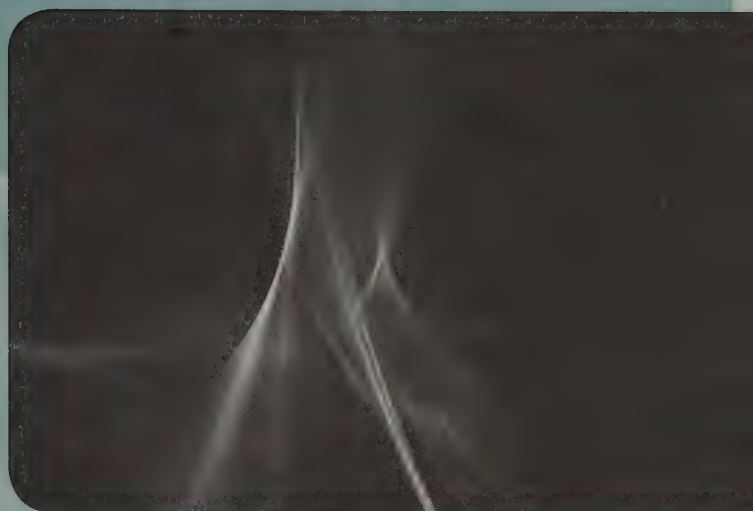
Date: 17 June 2008

National Audit Office

151 Buckingham Palace Road

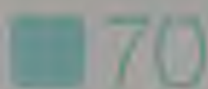
Victoria

London SW1W 9SS



08 Financial Accounts





Financial Accounts

Income and Expenditure Account for the Year Ended 31 March 2008

	Notes	2007/08	2006/07
Income			£
Gross Income	2	5,406,582	4,478,841
Expenditure			
Staff Costs	3	4,600,399	4,499,121
Other Operating Charges	4	2,915,087	2,061,490
Depreciation and Amortisation	5	425,215	494,097
Loss on Disposal of Fixed Assets		2,357	15,097
Total Expenditure		7,943,058	7,069,805
Net Operating Expenditure before Interest and Tax		(2,536,476)	(2,590,964)
Exceptional Item : Provision for legal costs payable	9	(78,000)	(450,000)
Interest Receivable		19,371	11,646
Less : Taxation		(4,619)	(4,000)
Notional Interest (Capital Charges)	1(h)	(48,309)	(80,825)
Net Expenditure on Ordinary Activities		(2,648,033)	(3,114,143)
Write back of Notional Interest	1(h)	48,309	80,825
Net Expenditure for the Financial Year	11	(2,599,724)	(3,033,318)

All operations are continuing.

Statement of Total Recognised Gains and Losses for the Year Ended 31 March 2008

	2007/08	2006/07
Net Expenditure for the Financial Year	(2,599,724)	(3,033,318)
Total Recognised Loss Relating to the Year	(2,599,724)	(3,033,318)

The notes on pages 73 to 88 form part of these Accounts.

Balance Sheet as at 31 March 2008

		31 March 2008	31 March 2007
			£
	Notes		
Fixed Assets	5	649,988	838,612
Current Assets:			
Debtors: Amounts Falling Due Within One Year	6	1,263,591	1,295,308
Cash at Bank and in Hand	7	551,545	494,403
Creditors: Amounts Falling Due Within One Year	8	(737,279)	(680,863)
Net Current Assets		1,077,857	1,108,848
Long Term Liabilities			
Provisions for Liabilities and Charges	9	(404,457)	(510,348)
Total Assets less Liabilities		1,323,388	1,437,112
Financed By			
Capital and Reserves			
General Reserve	11	1,323,388	1,437,112

The notes on pages 73 to 88 form part of these Accounts.



Mr Alan Doran CB
Interim Chief Executive
10 June 2008

Cash Flow Statement for the Year Ended 31 March 2008

		2007/08	2006/07
	Notes	£	£
Operating Activities			
Net Cash Outflow	17(a)	(2,173,725)	(1,795,897)
Capital Expenditure and Financial Investment			
Payments to Acquire Fixed Assets - Tangible	5	(229,203)	(41,410)
- Intangible	5	(25,930)	(25,600)
Cash Received on Disposal of Assets		0	7,380
Net Cash Outflow Before Financing		(2,428,858)	(1,855,527)
Financing			
Grant-in-Aid received towards Resource Expenditure	11	2,486,000	1,739,000
Net Cash Inflow from Financing		2,486,000	1,739,000
(Decrease) / Increase in Cash	17(b)	57,142	(116,527)

The notes on pages 73 to 88 form part of these Accounts.

As at 31 March 2008 there were fixed asset accruals amounting to £5,383 (2006/07: £21,568.)

Notes to the accounts:

1. Accounting Policies

(a) Accounting Convention

The HFEA's accounts are prepared in accordance with the provisions of the Human Fertilisation and Embryology Act 1990 and an Accounts Direction issued by the Secretary of State for Health in June 2007. The accounts are prepared, in accordance with generally accepted accounting practice in the United Kingdom (UK GAAP) and the Companies Act requirements, the disclosure and accounting requirements contained in HM Treasury's Managing Public Money, and the accounting and disclosure requirements given in HM Treasury's Financial Reporting Manual (FReM) insofar as these are appropriate to the HFEA and are in force for the financial year for which the statements are prepared. The financial statements are prepared under the modified historical cost convention by the inclusion of fixed assets at their value to the business by reference to current costs, where there is a material difference between historic cost and current replacement cost.

(b) Fixed Assets

Fixed Assets include tangible and intangible fixed assets and the costs of acquiring or creating computer systems or software. Only items, or groups of related items, costing £1,000 or more and with individual values over £250, are capitalised. Those costing less are treated as revenue expenditure.

Fixed assets are stated at their depreciated historical cost as the Authority considers this an appropriate basis for calculating their current value, after taking into consideration the estimated useful economic lives of the assets and their values.

(c) Grant-in-Aid

Grant-in-Aid received is used to finance activities and expenditure which support the statutory and other objectives of the entity are treated as financing and credited to the General Reserve, because they are regarded as contributions from a controlling party.

(d) Operating Income

Licence fee income is recognised at the time of treatment date. An estimate of the income for treatments provided by the clinics, but not reported to the HFEA at 31 March is accrued based on the historical data of the typical delay between the clinic providing the treatment to the patient and reporting the treatment to the HFEA.

Deferred income is recognised in respect of income for annual licence fees.

(e) Depreciation and Amortisation

Depreciation is provided on all tangible fixed assets on a monthly basis from the date of acquisition at rates calculated to write off the cost of each asset evenly over its expected useful life. Expected useful lives are as follows:

Computer equipment and software	3 years
Office equipment	4 years
Furniture, fixtures and fittings	4 years
Leasehold improvements	Length of lease to next breakpoint.

Amortisation is provided on intangible fixed assets (which comprise software licences) on a monthly basis at a rate calculated to write off the cost of each intangible asset over its expected useful life. The expected useful life of these software licences is 3 years.

(f) Operating Leases

Operating leases are charged to the accounts on a straight line basis over the lease term.

(g) Register of Information

Expenditure on development of the computer programme for the Register of Information is charged to the Income and Expenditure Account as it is incurred, with the exception of certain staff costs which are capitalised and are shown in note 5 to these accounts under "constructed software." No staff costs required capitalisation during financial year 2007/08.

(h) Notional Charges

In accordance with Treasury guidance, notional interest at 3.5% (2006/07 3.5%) of the average capital employed has been debited in the Income and Expenditure Account amounting to £48,309 (2006/07 – £80,825).

(i) Pensions

Past and present employees are covered by the provisions of the Principal Civil Service Pension Scheme (PCSPS.) The defined benefit elements of the scheme are unfunded and are non-contributory except in respect of dependents' benefits. The HFEA recognises the expected cost of these elements on a systematic and rational basis over the period during which it benefits from employees' services by payment to the PCSPS of amounts calculated on an accruing basis. Liability for payment of future benefits is a charge on the PCSPS. In respect of the defined contribution elements of the scheme, the HFEA recognises the contributions payable for the year.

Further information in respect of Civil Service Pensions is provided in the Remuneration Report.

(j) Disclosure of Fees and Costs Information

In accordance with the principles of HM Treasury's Managing Public Money and section 16 of the Human Fertilisation and Embryology Act 1990, the Authority sets its regulatory fees with the objective of recovering the full costs of the regulatory services it provides.

There are some elements of the Authority's work that do not relate directly to the regulatory process, and the Department of Health accordingly contributes to the funding of these activities proportionately as appropriate through the provision of annual Grant-in-Aid.

The key areas of work funded in this way are the maintenance of the Authority's register of IVF and Donor Insemination treatments and their outcomes; policy development and communications; the production of publications (that do not relate to the regulatory process); and associated overhead and management costs.

Grant-in-Aid is also received for the purchase of IT, furniture and other office equipment.

Further information in respect of Grant-in-Aid received in the year is provided in note 11 to these accounts.

(k) Change of Accounting Policy

As part of the preparations for the introduction of International Financial Reporting Standards (IFRS) which are planned to be implemented in the central government sector from April 2009, the Authority has estimated the value of annual leave accrued but not taken by staff at 31 March 2008, together with the value of annual leave taken in excess of holiday entitlement earned at that date.

£69,529 is recognised in "Accruals" in Note 8 in respect of annual leave accrued but not taken by staff at 31 March 2008 and £35,023 is recognised in "Other Debtors" in Note 6 in respect of annual leave taken in excess of holiday entitlement earned at 31 March 2008, with the corresponding entries reflected within staff costs in Note 3.

No adjustment has been made to prior period figures since the impact of this change in accounting policy is not considered to be material.

(l) Value Added Tax

The Authority was not registered for VAT during financial year 2007/08.

2. Gross Income

Gross income is made up of licence fee and other incomes which are recorded on an accruals basis.

Analysis of Income

	2007/08	2006/07
	£	£
Licence Fee Income	5,212,804	4,330,140
Other Income	193,778	148,701
Total Income for the Year	5,406,582	4,478,841

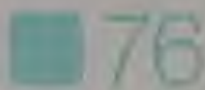
Other income relates primarily to the provision of financial, human resources, and legal services through a number of service level agreements with the Human Tissue Authority. Further information in respect of these transactions is provided in note 15 (c) to these accounts.

3. Staff Costs

	2007/08	2006/07
	£	£
(a) All Staff		
Salaries - HFEA Staff	3,271,136	3,333,784
Salaries - Seconded Staff	123,230	12,009
Social Security Costs	299,715	294,899
Superannuation Costs - Seconded Staff	28,155	2,734
Superannuation Costs - HFEA Staff	631,451	638,789
Agency/Temporary Staff	123,293	98,501
	4,476,980	4,380,716
Members' Costs	123,419	118,405
Total	4,600,399	4,499,121

(b) The average monthly number of full time and part-time staff employed, including secondees and temporary staff, during the year was as follows:

	2007/08	2006/07
Management	5	5
Administrative	85	89
Total	90	94



(c) Remuneration of Authority Members

Members' Costs (including Chair)	2007/08	2006/07
	£	£
Total fees payable to members	118,641	108,554
Social Security Costs	4,778	6,979
Superannuation Costs	0	2,872
	123,419	118,405

Members were also reimbursed for travel and subsistence incurred on HFEA business. Where this related to travel from the members' homes to the HFEA's office, the resulting tax liabilities were met by the HFEA under a PAYE settlement agreement.

4. Other Operating Charges

	2007/08	2006/07
Operating Lease Payments		£
-Land and Buildings	374,836	362,743
-Other Leases	9,795	8,579
Accommodation	267,975	247,321
Travel & Subsistence	289,384	257,908
Attendance Fees – External Advisors	13,925	4,320
Professional & Administrative Fees	729,671	310,009
Audit Fees		
- External (note 1)	42,850	38,150
- Internal	43,360	39,571
Register of Information (note 2)	0	8,916
Stationery, Photocopying & Printing	109,947	140,074
Telephones & Postage	67,034	78,348
Training & Development	112,423	110,211
Recruitment & Advertising	201,556	51,149
Communications, Opinion Research, Media Relations & Monitoring	301,207	126,161
Conferences & Meeting Expenses	108,394	78,708
Sundry Office Equipment	4,426	10,419
IT Costs (Including Website)	182,043	126,206
Miscellaneous	56,261	62,697
Total	2,915,087	2,061,490

Notes

1. The external audit fee from the NAO represents the cost for the audit of the financial statements carried out by the Comptroller and Auditor General. This account does not include fees in respect of non-audit work. No such work was undertaken by the NAO on behalf of the HFEA during the year.
2. Costs charged to the register of information include some expenditure relating to this project which would normally fall within other expenditure lines, such as some accommodation and related costs, recruitment and legal and professional fees, IT costs, and travel and subsistence.

Tangible and Intangible Fixed Assets at 31 March 2008

Tangible Fixed Assets	Leasing and Improvements	Information Technology	Office Equipment	Furniture & Fittings	Constructed Software	Totals
	£	£	£	£	£	£
Cost/valuation as at 1 April 2007	379,934	624,464	157,247	48,714	510,752	1,721,111
Additions	0	207,635	0	2,738	0	210,373
Disposals	0	(116,670)	(2,418)	0	0	(119,088)
As at 31 March 2008	379,934	715,429	154,829	51,452	510,752	1,812,396
Depreciation as at 1 April 2007	124,282	487,121	121,190	35,128	225,581	993,302
Charge for the year	45,775	105,770	20,229	7,148	170,250	349,172
Disposals	0	(114,313)	(2,418)	0	0	(116,731)
As at 31 March 2008	170,057	478,578	139,001	42,276	395,831	1,225,743
Net Book Value (NBV)						
At 31 March 2008	209,877	236,851	15,828	9,176	114,921	586,653
At 1 April 2007	255,652	137,343	36,057	13,586	285,171	727,809
Increase/(Decrease) in NBV	(45,775)	99,508	(20,229)	(4,410)	(170,250)	(141,156)

Intangible Fixed Assets

Intangible Fixed Assets	Software Licences	Total Intangible Fixed Assets	Total Tangible Fixed Assets	Grand Total of Fixed Assets
	£	£	£	£
Cost/valuation as at 1 April 2007	341,938	341,938	1,721,111	2,063,049
Additions	28,575	28,575	210,373	238,948
Disposals	0	0	(119,088)	(119,088)
As at 31 March 2008	370,513	370,513	1,812,396	2,182,909
Amortisation / Depreciation				
as at 1 April 2007	231,135	231,135	993,302	1,224,437
Charge for the year	76,043	76,043	349,172	425,215
Disposals	0	0	(116,731)	(116,731)
As at 31 March 2008	307,178	307,178	1,225,743	1,532,921
Net Book Value (NBV)				
At 31 March 2008	63,335	63,335	586,653	649,988
At 1 April 2007	110,803	110,803	727,809	838,612
Increase/(Decrease) in NBV	(47,468)	(47,468)	(141,156)	(188,624)



6. Debtors: Amounts Falling Due Within One Year

6 (a) Analysis by Type	31 March 2008	31 March 2007
	£	£
Licence Fee & Accrued Income	1,058,315	1,128,030
Balances with Central Government Bodies	19,170	69,670
Other Debtors	53,331	19,085
Prepayments	132,775	78,523
	1,263,591	1,295,308
6 (b) Intra – Government Balances		
Balances with Other Central Government Bodies	19,170	69,670
Balances with NHS Trusts	225,157	73,279
Total Intra – Government Balances	244,327	142,949
Balances With Bodies External to Government	1,019,264	1,152,359
	1,263,591	1,295,308

7. Cash at Bank and in Hand

	31 March 2008	31 March 2007
		£
Cash at Bank and in Hand	551,545	494,403

8. Creditors: Amounts Falling Due Within One Year

8 (a) Analysis by Type	31 March 2008	31 March 2007
	£	£
Trade Creditors	51,804	205,358
Accruals	617,208	468,342
Deferred Income	16,700	7,163
Other Creditors	51,567	0
	737,279	680,863
8 (b) Intra – Government Balances		
Balances with Other Central Government Bodies	12,558	0
Balances with NHS Trusts	10,341	0
Total Intra – Government Balances	22,899	0
Balances With Bodies External to Government	714,380	680,863
	737,279	680,863

9. Provisions for Liabilities and Charges

	Free Rent	Legal	Other	Total
	£	£	£	£
Balance at 1 April 2007	60,348	450,000	0	510,348
Provided in the Year	0	78,000	36,000	114,000
Paid in the Year	0	(210,000)	0	(210,000)
Release of Provision for Year	(9,891)	0	0	(9,891)
Total Provision for Liabilities and Charges	50,457	318,000	36,000	404,457

The lease for the premises that the HFEA currently occupy included a rent free period. The rent reduction given through the rent free period is spread over the term of the lease, up to the first break clause in 2012.

As noted in the Annual Report and Accounts for financial year 2006/07, Judicial Review proceedings were commenced against the HFEA in early 2007. Prior to the substantive hearing, the proceedings were disposed of by way of a consent order in which the HFEA agreed to pay 90% of the legal costs incurred



by the Claimant up to 26 March 2007, such costs to be subject to detailed assessment if not agreed. A provision of £450,000 was recognised as at the end of financial year 2006/07 for these costs. This provision was based on estimates taking into account information available at the time, and advice from law costs draftsmen.

Final agreement to the amount to be settled is yet to be reached, and accordingly the amount to be paid to the claimant is now subject to assessment. In the meantime, payments on account totalling £210,000 have been made in the year. Based on progress with this assessment to date, the provision for costs to be paid by the HFEA has been increased by £60,000, and a further provision for estimated interest on the amount to be paid in the sum of £18,000 also included.

The legal and professional fees of contesting actions brought against the Authority are accounted for in the period in which they arise.

10. Post Balance Sheet Events

Note 14 details the post balance sheet event regarding Judicial Review proceedings commenced against the HFEA before the end of the financial year.

These accounts are authorised to be issued on 17 June 2008.

11. Reserves

	General Reserve
At 1 April 2007	1,437,112
Net expenditure	(2,599,724)
Grant-in-Aid received towards Resource Expenditure	2,399,000
Grant-in-Aid received towards Purchase of Fixed Assets	87,000
Balances at 31 March 2008	1,323,388

Grant-in-Aid received from the Department of Health included contributions from the devolved administrations for Scotland, Wales and Northern Ireland.

12. Financial Commitments

The HFEA is committed to make the following operating lease payments during next financial year:

	2007/08	2006/07
Land and Buildings		
Leases which expire within 1 year	0	0
Leases which expire within 2 to 5 years	0	0
Leases which expire after 5 years	403,524	384,728
Other Leases		
Leases which expire within 1 year	3,531	0
Leases which expire within 2 to 5 years	0	8,580

13. Capital Commitments

At the balance sheet date the HFEA had no capital commitments (2006/07 nil).

14. Contingent Liabilities

A number of legal proceedings were initiated against the Authority which relate to the financial year 2007/08.

In October 2007, the Authority was served with an application seeking permission for judicial review in respect of a decision (made by the Licence Committee in July 2007) not to grant a licence to a centre. On 23 May 2008, the Authority was notified that the Court had refused permission. However, the Claimant has a right to renew his application. At this point in time, it is not possible to predict with certainty the outcome of this action, or any resultant financial impact on the Authority.

In June 2007, the Authority was joined to proceedings in the Family Court relating to the harvesting of gametes without consent. Further proceedings have now been issued seeking a declaration that the Human Fertilisation and

Embryology Act 1990 is incompatible with the Human Rights Act 1998, and declarations relating to the storage and export of gametes. At this stage in the proceedings, it is not possible to predict with any certainty the outcome of this action, or any resultant financial impact on the Authority.

In January 2008, the Authority's Research Licence Committee issued two research licences. This decision is now the subject of an application for judicial review which was issued against the Authority in April 2008. The claimants seek a declaration that the Authority acted unlawfully and had no power to grant such a licence. At this stage in the proceedings, it is not possible to predict with any certainty the outcome of this action, or any resultant financial impact on the Authority.

15. Related Party Transactions

The Department of Health is regarded as a related party. During the year the HFEA had various material transactions with the Department of Health and with some NHS Trusts for which the Department of Health is regarded as the parent Department.

- a) During the year the HFEA invoiced the Department of Health £201,728 for staff costs relating to the secondment of three members of staff, including the Authority's Chief Executive Ms Angela McNab, together with £11,004 costs relating to training, travel and subsistence, and sundry staff costs in respect of Ms McNab. The Department of Health invoiced the Authority £164,237 during the year in respect of their secondment to the HFEA of three members of staff, including the interim Chief Executive Mr Alan Doran CB.

As at 31 March 2008 the HFEA owed the Department of Health £240.

- b) The following members of the HFEA board have senior management responsibilities at either NHS Trusts or private clinics that are regulated by the HFEA:

Mr Hossam Abdalla, Director of the Lister Fertility Clinic. Fees invoiced by the HFEA to the Lister Hospital during the year amounted to £242,112. The balance on the Lister's account as at 31 March 2008 was £31,924.

Professor Christopher Barratt Scientific Director of Ninewells Hospital, Dundee (from 3rd March 2008.) Fees invoiced by the HFEA to Ninewells Hospital during the year amounted to £64,650. The balance on Ninewells Hospital's account as at 31 March 2008 was £5,485.

Professor Neva Haites OBE, Vice Principal and Head of College of Life Science and Medicine, University of Aberdeen. Fees invoiced by the HFEA to the University of Aberdeen during the year amounted to £41,658. The balance on the University of Aberdeen's account as at 31 March 2008 was £19,751.

Dr Maybeth Jamieson, Consultant Embryologist at the Assisted Conception Service, Glasgow Royal Infirmary. Fees invoiced by the HFEA to Glasgow Royal Infirmary during the year amounted to £181,512. The balance on the Glasgow Royal Infirmary's account as at 31 March 2008 was £34,033.

Professor William Ledger Person

Responsible for the Centre for Reproductive Medicine and Fertility, Sheffield. Fees invoiced by the HFEA to the Centre for Reproductive Medicine and Fertility during the year amounted to £87,643. The balance on the Centre's account as at 31 March 2008 was £5,068.

Mr Roger Neuberg, Consultant Obstetrician and Gynaecologist at the Leicester Royal Infirmary. Fees invoiced by the HFEA to Leicester Royal Infirmary during the year amounted to £48,335. The balance on the Leicester Royal Infirmary's account as at 31 March 2008 was £12,962.

As at 31 March 2008 it was anticipated that there was, in addition to the sums noted above, some accrued income due from the above mentioned clinics. This sum is estimated in its totality, based on a global average of treatment reporting delays and the amount due from each clinic cannot be quantified precisely as at the date of signing these accounts.

- c) The Human Tissue Authority (HTA) is regarded as a related party for financial year 2007/08, as under Government proposals at the beginning of the year it was intended that this body would be merged with the HFEA to create a new regulatory body, the Regulatory Authority for Tissue and Embryos (RATE.)

With effect from 1 January 2007, **Shirley Harrison** was appointed as Chair of both the HFEA and HTA. **Ms Sharmila Nebhrajani** is Deputy Chair of the HFEA, and was also a member of HTA until 1st August 2007.

The Government response on 8th October 2007 to the Joint Committee on the Human Tissue and Embryos (draft) Bill stated that RATE would not be formed, and that the HFEA and HTA would be retained as separate regulatory authorities.

Shirley Harrison resigned as Chair of the HFEA on 31 October 2007.

During the year the HFEA invoiced HTA £6,266 for secretarial support to **Shirley Harrison**, £176,324 for the provision of human resources, training, IT, legal, and finance services, and £52,444 for the reimbursement of recruitment, payroll, training and sundry staff costs.

HTA invoiced the HFEA £42,120 during the year in respect of salary and travel and subsistence costs in respect of Shirley Harrison, and also IT costs. As at 31 March 2008 HTA owed the HFEA £19,410 and the HFEA owed HTA £8,225.

- d) Clare Brown** is the Chief Executive of Infertility Network UK. A payment of £452 was made to Infertility Network UK by the HFEA during the year for reimbursement of travel and subsistence expenses incurred by Clare Brown and other members of the organisation in respect of HFEA business.
- e)** In the Annual Report all Members' interests are disclosed and Members are expected to declare any conflict of interest in discussions held by the Authority. A system to record conflicts of interests involving staff of the HFEA was implemented in September 2003.

16. Performance against Key Financial Targets

During the year, the HFEA managed income and expenditure so that draw downs were kept to within the Department's cash allocation. A total of £2,426,000 was drawn down from the Department during the year, out of a total available cash allocation of £2,426,000. A further sum of £60,000 was provided as a grant to the Authority from the Sciencewise programme run by the then Department of Trade and Industry (now the Department for Innovation, Universities and Skills) as a contribution to a public consultation project undertaken during the year.



17. Notes to the Cash Flow Statement

	2007/08	2006/07	
	£	£	
a. Reconciliation of Operating Surplus to Net Cash Outflow From Operating Activities:			
Net Expenditure for the Financial Year	(2,599,724)	(3,033,318)	
Loss on Disposals of Fixed Assets	2,357	15,097	
Depreciation Charges	425,215	494,097	
Decrease in Debtors	31,717	139,424	
Increase in Creditors	72,601	149,491	
Amounts provided in the year (legal costs payable)	78,000	450,000	
Amounts provided in the year (other provisions)	36,000	0	
Use of Provisions (free rent)	(9,891)	(10,688)	
Payment of Provisions (legal)	(210,000)	0	
Net Cash Outflow from Operating Activities	(2,173,725)	(1,795,897)	
b. Analysis of Changes in Cash			
	At 31 March 2007	Cash Flows	At 31 March 2008
	£	£	£
Cash at Bank and in Hand	494,403	57,142	551,545

18. Financial Instruments

FRS 13, Derivatives and Other Financial Instruments, requires disclosure of the role financial instruments have had during the period in creating or changing the risks an entity faces in undertaking its activities.

As permitted by FRS 13, debtors and creditors which mature or become payable within 12 months from the balance sheet date have been omitted from this note.

a) Liquidity Risk

66% of total gross income (including Grant-in-Aid) during the year was derived directly from the number of IVF and DI treatment cycles performed by the licensed clinics and reported to the HFEA, together with licences issued to clinics. The remaining main source of revenue is derived from Government grants made on a cash basis.

There are procedures in place to identify late and non-reporting of treatment cycles by clinics and also procedures for chasing up debts. The HFEA is therefore not exposed to significant liquidity risks.

b) Investments and Interest Rate Risk

The HFEA follows an investment policy of placing any surplus funds on deposit in an interest bearing bank account. Gross interest income was £19,371 of the revenues of the HFEA, and the HFEA is not therefore exposed to significant interest rate risk.

c) Financial Assets

	Total	Non-Interest bearing cash deposits	Floating-rate cash deposits
	£	£	£
At 31 March 2008	551,545	-	551,545
At 31 March 2007	494,403	-	494,403

Petty cash held on site amounted to £517 (2006/07: £3,500).

The fair value of the financial assets was equal to the book value.

d) Financial Liabilities

The HFEA had no financial liabilities at 31 March 2008 requiring disclosure under FRS 13.

e) Foreign Currency Risk

There were minimal foreign currency transactions conducted by the HFEA during the year ended 31 March 2008. There was therefore no significant foreign currency risk during the year.

19. Losses and Special Payments

No losses or special payments either individually or totalling over £250,000 were made in the year ended 31 March 2008.



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